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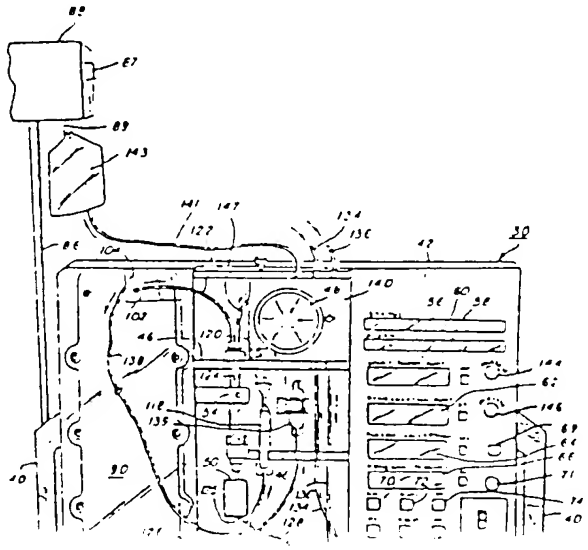
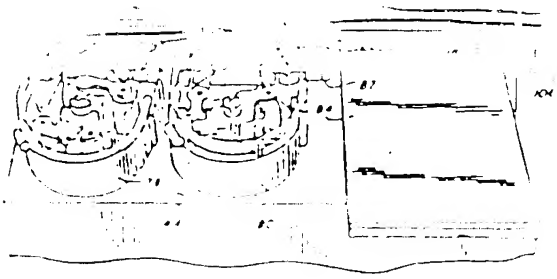
(57) Abstract

A blood fractionation apparatus is provided and includes a main housing (30) carrying pumps (78, 80), a cell housing (49) for receiving a disposable blood fractionation filter membrane cell (90), and electrical control apparatus. The main housing (30) has a panel (42) defining a number of slots for receiving disposable blood flow tubing within predetermined slots. The housing (30) carries an occluded vein sensor (82) and a bubble detector (54) for cooperation with the tubing, and a manually operable mode switch (48) is provided for setting control function of the apparatus. The apparatus will cease operating if the mode switch (48) is set incorrectly or if an irregularity is sensed. The apparatus also includes an alarm (200), an alarm





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BLOOD FRACTIONATION APPARATUS

BACKGROUND OF THE INVENTION

This invention concerns a novel blood fractionation apparatus.

As used herein, the term "blood fractionation" includes the separation and/or treatment of any fraction of whole blood, including but not limited to plasma, red cells, white cells, platelets and cryoprecipitate.

Typical blood fractionation techniques utilize the collection of whole blood from donors in bags, and removal of the bags to a centrifuge where the blood fraction is separated from the whole blood. The blood fraction is withdrawn from the bag and the remaining blood is returned to the donor.

One significant blood fraction which has been withdrawn by centrifugation for many years is plasma. In certain plasmapheresis techniques, a bag containing whole blood is placed in a centrifuge where the plasma is separated and the remaining blood is returned to the donor.

More recently, automated centrifuges have been devised which continuously withdraw whole blood from

maining blood in its plasma-poor condition to the donor in a continuous fashion.

It has been proposed that the plasmapheresis be carried out without using a centrifuge, because of the inherent complexity and cost of centrifugation equipment. To this end, the filtration of cells from whole blood using a microporous membrane has been disclosed, for example, in Blatt, et al. U.S. Patent No. 3,705,100. It has been found that a membrane-type plasmapheresis device yields platelet-free plasma while centrifuge devices yield plasma containing some platelets. Further, it has also been found that the membrane plasmapheresis devices can also be designed to yield much greater quantities of plasma in shorter times than the centrifuge devices.

A membrane plasmapheresis apparatus, in which a relatively inexpensive, disposable plasmapheresis filter membrane cell is utilized, is disclosed in DeVries, et al. U.S. patent application Serial No. 942,077, filed September 13, 1978. Another membrane plasmapheresis filter cell of the disposable type is disclosed in DeVries, et al. U.S. patent application Serial No. 971,905, filed December 21, 1978. In these copending patent applications, a parallel membrane type of membrane plasmapheresis apparatus is disclosed, and the filter cells disclosed therein are relatively simple in construction and inexpensive to produce.

On occasions, it is desired to treat the plasma filtrate with an agent for detoxification, cleansing, transformation, reaction, elimination of matter, [illegible] treatment characteristics

et al. patent application Serial No. 7,487, filed January 29, 1979. In application Serial No. 7,487,

a system is disclosed in which the plasma may be treated without requiring the plasma to be filtered directly through a treatment reaction chamber.

Experiments with membrane plasmapheresis filter cells have shown their usefulness. It has been found desirable to provide relatively automated equipment that may be used conjointly with the disposable membrane filter cells, to achieve effective blood fractionation.

It is, therefore, an object of the present invention to provide blood fractionation apparatus which comprises "hardware", that is, a machine that is used to receive and use "software", in the form of tubing and a disposable filter cell.

Another object of the present invention is to provide blood fractionation apparatus which is self-containing and carries the pumps and control equipment which are required for the blood fractionation process.

A further object of the present invention is to provide blood fractionation apparatus which utilizes digital electronic technology for reliability and relative simplicity.

A still further object of the present invention is to provide blood fractionation apparatus which is relatively simple in construction and efficient to manufacture.

Another object of the present invention is to provide blood fractionation apparatus which is extremely safe and reliable to use, and which includes a fail-safe circuit and safety devices for preventing the apparatus from operating improperly.

A further object of the present invention is to provide an apparatus that is especially suited for continuous blood fractionation, in which the blood is withdrawn from a donor or patient, and the fraction is removed while the remainder of the blood is continuously returned to the donor or patient.

Another object of the present invention is to provide blood fractionation apparatus which includes memory means operative to prevent incorrect actuation of the apparatus.

A further object of the present invention is to provide blood fractionation apparatus which can be easily operated by a physician or nurse and which displays appropriate information to the operator.

Other objects and advantages of the present invention will become apparent as the description proceeds.

BRIEF DESCRIPTION OF THE INVENTION

In accordance with the present invention, blood fractionation apparatus is provided which comprises a main housing carrying at least one blood pump, a cell housing for receiving a disposable blood fractionation filter membrane cell, electrical control apparatus and means for coupling the housing to a source of electric current.

In the illustrative embodiment, the main housing has a panel defining a plurality of slots for receiving disposable blood flow tubing within predetermined slots. The housing carries an occluded vein sensor and a bubble detector for cooperating with the tubing. Pressure sensing means is provided for sensing pressure adjacent the disposable cell. The housing has a manually operable mode switch for setting control functions of the apparatus.

In the illustrative embodiment, programmed means are provided for preventing incorrect actuation of predetermined control functions. A door member covers at least a portion of the slots to prevent access thereto. Means inhibit operation of the door member and thus access to the slots unless the manually operable mode switch is in a predetermined position.

In the illustrative embodiment, the housing carries a safety clamp for clamping the tubing to restrict flow therein. Control means are coupled to the safety clamp and to the pump for inhibiting operation of the pump when the tubing is clamped. Audible alarm means are provided for signalling selected malfunctions during selected modes while other functions are inhibited.

The apparatus of the illustrative embodiment also includes an anticoagulant pump and means for carrying a supply of anticoagulant. The presence of anticoagulant is sensed and operation of the pump is inhibited if no anticoagulant is sensed.

The apparatus of the illustrative embodiment includes a fail-safe circuit coupled to the safety clamp, bubble detector and pump. The fail-safe circuit includes delay means and means for terminating operation of the apparatus in response to a predetermined signal from either the safety clamp, bubble detector or pump, after a predetermined delay from receipt of the predetermined signal.

In the illustrative embodiment, the electrical control apparatus is operable to set control functions of the apparatus. The control functions comprise a plurality of operational modes and the electrical control apparatus includes means for providing a signal representing each mode, means for encoding the mode signals to output a highest priority signal only, a comparator, programmed memory means for storing proper mode sequence data, means for feeding the encoded mode signal to an input of the programmed memory means, means for feeding the encoded mode signal to the comparator, and means for feeding the memory means output to the comparator. The comparator is operable to compare the encoded mode signal with the memory means output. Means are coupled to the output of the comparator for providing (a) a first signal if there is a first relationship between the encoded mode signal and the memory means output, and (b) a second signal if [illegible] a second relationship between the encoded mode

include a load mode enabling the fractionation apparatus to be loaded with disposable tubing, a prime mode for [illegible] with a selected liquid, a bypass mode

for withdrawing whole blood from a donor and passing the whole blood through the membrane cell but returning all blood components to the donor, and a collect mode for collecting one of the separated components while returning other blood components to the donor. The control functions also include an irrigate mode in which the apparatus is not functioning to collect one of the separated components, but a selected solution is provided to maintain venal punctures open and the tubing clean. The control functions further include a reinfuse mode in which the other blood components within the tubing are reinfused to the donor after one of the separated components is collected.

In the illustrative embodiment, the blood fractionation apparatus includes a whole blood pump, a recirculation pump, speed control means coupled to the whole blood pump and recirculation pump, blood flow tubing, means for sensing (a) the whole blood pump rate, (b) the recirculation pump rate, (c) blood pressure, (d) amount of blood component that is collected, (e) air bubbles in the tubing and (f) hemolysis. Display means are provided for displaying predetermined control functions and an alarm circuit is present for providing an audible alarm resulting from the sensing of predetermined conditions. Safety clamping means are provided for clamping the tubing under predetermined conditions. A fail-safe circuit is coupled to the safety clamping means, air bubble sensing means and pumps. The fail-safe circuit includes delay means and means for terminating operation of the apparatus in response to a predetermined signal from either the clamping means, air bubble sensing means or pumps, after a predeter-

illustrated in the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a perspective view of blood fractionation apparatus constructed in accordance with the principles of the present invention;

FIGURE 2 is a front view of the top panel thereof;

FIGURE 3 is a top view of the shelf thereof;

FIGURE 4 is a view of the plasma collection scale thereof;

FIGURE 5 is a perspective view of the occluded vein sensor carried by the apparatus of FIGURE 1;

FIGURE 6 is an enlarged fragmentary view of the manually operable mode switch carried by the apparatus of FIGURE 1, with the door in its closed position;

FIGURE 7 is a view similar to the view of FIGURE 6, with the door in its open position;

FIGURE 8 is a fragmentary view of another portion of the panel of the FIGURE 1 apparatus;

FIGURE 9 is a fragmentary view of another portion of the front panel of the apparatus of FIGURE 1;

FIGURE 10a, 10b and 10c, when connected together, comprise a block diagram of the elements and circuitry of blood fractionation apparatus constructed in accordance with the principles of the present invention;

FIGURE 11a and 11b, when connected together, comprise a schematic circuit diagram of the mode circuit of blood fractionation apparatus constructed in accordance with the principles of the present invention;

FIGURE 12 is a schematic circuit diagram of the pump start circuit apparatus constructed in accordance with the principles of the present invention;

cordance with the principles of the present invention;

FIGURE 14 is a schematic circuit diagram of the pump control circuit constructed in accordance with the principles of the present invention;

FIGURE 15 is a schematic circuit diagram of the alarm circuit of apparatus constructed in accordance with the principles of the present invention;

FIGURE 16 is a schematic circuit diagram of the clamp circuit of apparatus constructed in accordance with the principles of the present invention;

FIGURE 17 is a schematic circuit diagram of the fail-safe circuit of blood fractionation apparatus constructed in accordance with the principles of the present invention; and

FIGURE 18 is a schematic circuit diagram of the basic fail-safe power system of blood fractionation apparatus constructed in accordance with the principles of the present invention.

DETAILED DESCRIPTION OF THE ILLUSTRATIVE EMBODIMENT

Referring to FIGURES 1-3 in particular, a main housing 30 is carried by an upright 32 which is generally L-shaped and includes a base 34 to which casters 36 are connected. A series of ladder rungs 38 are provided to enable housing 30 to be moved vertically as desired for proper height positioning, and a handle 40 is provided for enabling the housing 30 and base 34 to be moved along the floor.

Housing 30 includes a front panel 42 and a shelf 44, with front panel 42 carrying display windows and control switches, racks 46 for receiving disposable blood flow tubing, a manually operable mode switch 48 for setting control functions of the apparatus, and a cell housing 49 for receiving a disposable blood fractionation filter membrane cell.

Panel 42 also carries a tubing clamp 50, a hemolysis detector 52 and a bubble detector 54. Tubing clamp 50, hemolysis detector 52 and bubble detector 54 are connected to cooperate with the disposable tubing that is carried by rack 46.

The display windows preferably allow the visibility of light emitting diodes which indicate various conditions. For example, the status of the apparatus is displayed at window 56, the various alarms or malfunctions are displayed at window 58, the whole blood pump rate is displayed at window 60, the recirculation pump rate is displayed at window 62, the plasma collection volume is displayed at window 64 and the membrane

start switch in the form of a push button 70, an

emergency stop switch 71, mute alarm switch in the form of a push button 72 for muting the alarm sound, a sensor override switch 74 in the form of a push button for overriding a particular sensor that is in an alarm condition and a reset switch 76 in the form of a push button.

The shelf 44 supports blood pump 78 and recirculation pump 80. Pumps 78 and 80 are peristaltic pumps, with their motors being enclosed within the housing 30. Shelf 44 also supports an occluded vein sensor 82 and a writing surface 84. While in the illustrative embodiment the anticoagulant pump is not carried by the housing, if desired, the anticoagulant pump could be held on an upright pole 86 and powered by means of an auxiliary power receptacle.

Upright pole 86 is connected to the housing 30 for supporting a plasma collection scale 88 and an anticoagulant liquid detector 87. Plasma collection scale 88 includes a hook 89 for receiving a plasma collection container, preferably in the form of a plastic bag defining a hole for being received by hook 89.

Cell housing 49 encloses a membrane cell 90, as illustrated in FIGURE 2. Cell 90 may comprise a disposable plasmapheresis membrane cell as described in De Vries, et al. U.S. patent application Serial No. 942,077, filed September 13, 1978 or a disposable cell as described in De Vries, et al. U.S. patent application Serial No. 971,905, filed December 21, 1978.

Referring to FIGURE 2 in particular, port 100 is the whole blood inlet and port 102 is the red

which is connected to the donor's vein for the withdrawal of whole blood. A Y-site inlet 107 is coupled [illegible]

outlet 108 is connected to whole blood tubing 110. Whole blood tubing 110 is coupled through occluded vein sensor 82 and it extends through pump 78, and to a Y-site 112. From the Y-site, the whole blood travels through tubing 114 to whole blood inlet 100 and also through tubing 116 to a pressure reservoir 118. A pressure transducer is connected to pressure reservoir 118 for measuring the pressure with respect to whole blood flow line 116. A sterile barrier 120 is provided between the pressure reservoir 118 and the pressure transducer.

A blood outlet line 122 is coupled to red cell outlet 102 and the red cells flow via line 122 through bubble trap 124 and tubing clamp 50 and to a Y-site 125 below clamp 50. Recirculation tubing 126 is coupled to one of the arms of the Y so that the red blood cells will flow via tubing 126, through pump 80 and for recirculation via tubing 114 into blood inlet 100. The other arm of Y-site 125 is coupled to tubing 128 so that some of the red cells will flow via tubing 128 to another Y-site 130 and then via tubing 132 back to the donor. A saline line 134 is connected to the other arm of the Y-site 130 for providing saline to the donor. A saline line 136 is also coupled to occluded vein sensor 82 for priming the system and for maintaining patency of the needle.

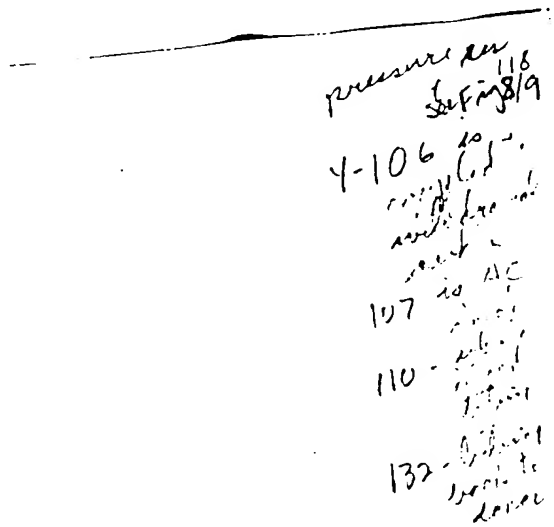
Tubing 138 is connected to plasma outlet 104 and the plasma will flow via tubing 138 and through an optical density chamber 139 and then tubing 141 to the plasma collection bag 143.

with one arm of the Y being coupled to tubing 141 and the other arm of the Y being coupled to a bypass line 147. Bypass line 147 returns the plasma to the

bubble trap 124. The purpose of the bypass line is that during start-up, a substantial amount of saline is found mixed with the plasma. This is detected by the hemolysis detector 52 and the plasma mixed with saline will flow in the bypass line 147 until line 138 and optical density chamber 139 shows relatively clear plasma. At that stage, the hemolysis detector 52 will sense the relatively clear plasma and the "collect plasma" lamp will be energized to indicate to the operator that rotary mode switch 48 can be turned to the "collect" mode.

Hemolysis detector 52 may be constructed in accordance with the disclosure in a patent application entitled, "Photometric Apparatus and Method", naming Richard I. Brown, Arnold C. Bilstad and Michael Wicnienski as inventors, Serial No. 127,732, filed March 6, 1980. Bubble detector 54 may be constructed in accordance with the disclosure of a U.S. patent application entitled "Liquid Absence Detector", naming as inventors Arnold C. Bilstad and Michael Wicnienski, Serial No. 127,552, filed March 6, 1980. Occluded vein sensor 82 may be constructed in accordance with the disclosure of a U.S. patent application entitled, "Liquid Flow Sensing Apparatus", naming Richard I. Brown as inventor, Serial No. 127,554, and filed March 6, 1980. The plasma scale used in connection with plasma chamber 88 may be constructed in accordance with the disclosure of a U.S. patent application entitled, "Apparatus and Method For Weighing Material Being Collected", naming Arnold C.

[illegible] may be constructed in accordance with the disclosure of the U.S. patent application entitled,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"Control System For Fluid Flow Apparatus", naming Arnold C. Bilstad and Richard I. Brown as inventors, Serial No. 139,884, and filed on the same day as the present application. Cell housing 49 may be constructed in accordance with the disclosure of a U.S. patent application entitled, "Method and Apparatus For Obtaining a Desired Rate of Plasma Collection From a Membrane Plasmapheresis Filter", naming Richard I. Brown and Arnold C. Bilstad as inventors, Serial No. 127,733, and filed on March 6, 1980. Anticoagulant detector 87 may be constructed in accordance with the disclosure of a United States patent application entitled, "Liquid Presence Detector", naming Arnold C. Bilstad and Richard I. Brown as inventors, Serial No. 127,553, filed March 6, 1980.

In order to understand the functions of the previously-described structure and the circuitry to be described below, a brief description of the operation of the system will now be set forth.

First, mode switch 48 is rotated to "load" position and door 100, on which the mode switch 48 is carried, is opened from its closed position as illustrated in FIGURE 6 to its open positions as illustrated in FIGURE 7. It can be seen that door 140 is hinged at 142. The disposable tubing and equipment are then inserted into the slots of the slotted racks 46 as illustrated in FIGURES 2 and 7-9. Once all of the disposable lines are properly connected and inserted into the slotted racks 46 as described [illegible] closed and "on" switch 68 is turned

[illegible] lected. The whole blood pump speed is set by means of dial 144 and the recirculation pump speed is set by [illegible]

From "load" position, the dial switch 48 is turned to "prime" position and the system is primed. After priming the system, the lines 110 and 132 are coupled to the donor and the procedure may then commence. Dial switch 48 is turned to its "bypass" position. In this position, the donor's blood is withdrawn via tubing 110, passed through membrane cell 90, and both the red blood cells and the plasma are returned to the donor instead of the plasma being collected. In this manner, the priming solution (e.g., saline solution) is flushed out of the system and not collected.

Once hemolysis detector 52 senses that plasma is present instead of saline, status display 56 displays "collect plasma" and the operator may then turn dial switch 48 to its "collect" position. In the collect position, the plasma filtrate from membrane cell 90 is transferred via line 138, chamber 139 and line 141 to the plasma collection container 143 that hands from hook 89 while the red cells are returned to the donor via lines 122, 128 and 132.

Dial switch 48 is manually operated and carries an electrical switch which follows the mechanical turning of the dial switch. The system is programmed so that the operation will terminate if the dial switch is turned improperly, such as in the wrong direction or from one mode to the wrong mode. For example, if the dial switch is incorrectly turned from "bypass" to "prime", the status display will show "mode switch" and shortly thereafter the system will shut off. Any other incorrect turning of the dial switch will cause the "mode switch" readout to occur on display 56 and shortly thereafter the system will turn off. In the

56 shows "mode switch" but there is a delay preventing the system from being turned off so that the operator has time to move from one position on dial switch 48 to another position of the dial switch.

Door 140 cannot be opened unless dial switch 48 is in its "load" position. Referring to FIGURE 7, at the back of dial switch 48 there is a keyway 150 which fits on a key 152. When dial switch 48 is turned, keyway 150 also turns key 152 which is coupled to various camming members that appropriately clamp the tubing that is within the housing. A detailed description of switch 48 is set forth in Bilstad and Brown U.S. application for "Control System For Fluid Flow Apparatus", Serial No. 139,884, filed on the same date as the present application.

In order to start the pumps moving, the system has to be armed by unclamping tubing clamp 50. Tubing clamp 50 comprises a pair of magnetically coupled levers which must be squeezed together to unclamp the tubing. Once the tubing is unclamped, pump start button 70 may be pressed and the pumps will start slowly at first and then increase speed automatically.

The two levers which form the clamp and which are pushed together to unclamp the tubing are coupled together by means of an electromagnet. If for some reason the two levers are forced apart or the electromagnet fails so that they come apart, the tubing clamp will clamp the tubing and the pumps will immediately stop, as the system is programmed to prevent operation of the pumps while the tubing is being clamped. When the tubing is clamped and the levers are apart, [illegible] "return clamped" and when

[illegible]

It can be seen that the machine is manually operated and under the control of the operator. In order for the machine to operate, the operator must perform certain positive actions. In effect, there are certain allowed modes while other modes are incorrect and will operate to shut off the system. Once the system is shut off, it will have to be reset as if it had not been operating previously. Thus once the system is shut off, the tubing will be clamped and the two levers must again be pressed together in order to arm the system. Further, if mute switch 72 was previously on to prevent the alarm from sounding, once the system is shut off the mute switch will not go on automatically when the system is restarted. The mute switch 72 will again have to be pressed.

If during the "collect" mode there is a problem and the operator desires to discontinue the collection of plasma temporarily, the rotary switch 48 can be turned to "irrigate". In the "irrigate" mode, the machine is shut down and there is no plasma collection, but the saline is dripping to keep the venapunctures open and the lines clear.

When the required amount of plasma has been collected, as set by end point switch 69, such as 550 or 650 ml, the alarm activates and there is a readout on display 56 saying "collection complete". This is effectively a weight measurement. Once the collection is completed, no further collection can be performed nor can the system start again, even if switch 48 is in the "collect" or the "bypass" mode.

The "reinfuse" mode may be used after the plasma is collected. After collection, the rotary switch

the tubing to push the red cells that are within the system back into the donor's veins. The rotary switch 48 is then turned to its "load" position and this effectively becomes an "unload" mode because the combination of "load" with the weight of the full plasma collection container 143 allows everything to be removed for another collection. Thus the "unload" mode is really the "load" position of switch 48 in combination with the weight of a full plasma container. To get back to the "load" mode, the plasma container is removed from hook 89 and another collection via the machine can be performed.

The system is programmed so that inadvertent turning of the rotary switch can be overridden. For example, assume that the switch is in its "collection" mode and then turned to "irrigate", which is an allowed operation. Now assume that the operator wishes to turn back to "collect" but inadvertently turns the rotary switch 48 to "reinfuse". The system will then shut off. However, in order to prevent having to start everything up again, the operator can turn the rotary switch 48 back to "collect" where he wants to be. He can then push the reset button 76 and a resume button 156 simultaneously and the program will be overridden so that the system goes directly into the mode that is shown on switch 48.

A block diagram of the basic system is set forth in FIGURES 10a-10b-10c, when these Figures are connected together.. The various sensors or detectors are shown on the left side of the diagram and include a whole blood pump tachometer 160, a recirculation pump to membrane cell 90, a plasma strain gauge 166 for

weighing the collected plasma and forms a part of scale 88, an ACD presence sensor 87, bubble detector sensor 54, occluded vein sensor 82, and hemodetector sensor 52. Whole blood pump tachometer 160 is coupled to whole blood sensor circuit 170 via line 171 and circuit 170 is coupled to whole blood pump rate and volume display 60 via line 172. Tachometer 160 is also coupled to fail-safe circuit 174 via lines 171 and 175 and an emergency stop switch 173 is also coupled to fail-safe circuit 174.

Recirculation pump tachometer 162 is coupled to recirculation pump circuit 176 via line 177 and to fail-safe circuit 174 via lines 177 and 178. Recirculation pump circuit 176 is coupled to recirculation pump rate display 62 via line 179.

Membrane pressure sensor 164 is coupled to membrane pressure preamplifier 180 which is coupled to membrane pressure circuit 182 via line 183. Circuit 182 is coupled to membrane pressure display 66 via line 184.

Plasma strain gauge 166 is coupled to plasma scale preamplifier 186 via line 187. Preamplifier 186 is coupled to a plasma scale circuit 188 via line 189. Circuit 188 is coupled to plasma volume display 64 via line 190.

ACD sensor 87 is coupled to an ACD detector preamplifier 192 via line 193. Preamplifier 192 is coupled to the plasma scale preamplifier via line 194. Line 189 couples the output of the plasma scale preamplifier 186 to an ACD detector circuit 196, the output 198 of which is connected to alarm circuit 200. Fail-safe circuit 174 is also connected to alarm

via line 204. The output of alarm circuit 200 is

connected via line 205 to alarm display 58. Alarm display 58 has the capacity to show the following readout if a malfunction with respect to one of the following items occur: "bubble detector", "occluded vein", "hemolysis detector", "membrane pressure", "ACD empty" and "fail-safe".

Bubble detector sensor 54 is coupled to bubble detector circuit 206 via line 207. The output of bubble detector circuit 206 is coupled via line 208 to fail-safe circuit 174 and another output of bubble detector circuit 206 is coupled via line 209 to alarm circuit 200. Occluded vein sensor 82 is coupled to alarm circuit 200 via line 210. Hemodetector sensor 52 is coupled to hemodetector circuit 212 via line 213, with the output of hemodetector circuit 212 being coupled to alarm circuit 200 via line 214.

Sensor override switch 74 is coupled to alarm circuit 200 via line 216 and to status display 56 via line 218. Reset switch 76 is coupled to alarm circuit 200 via line 219 and to mode circuit 220 via line 221. Resume switch 156 is coupled to mode circuit 220 via line 222 and mode switch 48 is coupled to mode circuit 220 via reinfuse signal line 224, irrigate signal line 225, collect signal line 226, bypass signal line 227, prime signal line 228, and load signal line 229.

The output of mode circuit 220 is connected to pump control circuit 230 via lines 231, 232. Pump on/off switch 70, whole blood speed pump control 144 and recirculation pump control 146 are also connected to pump control circuit 230 via lines 233, 234 and 235, respectively. Pump control circuit 230 is

via line 243, and fail-safe relay 242 is connected to

motor control 236 and 238 via lines 244 and 245, respectively.

The plasma scale circuit 188 is connected to mode circuit 220 via line 246. Line 246 also couples the plasma scale circuit to mute circuit 248, the output of which is coupled to an audible alarm 250. When mute switch 72 is actuated, the audible alarm will be deactivated.

Alarm circuit 200 is coupled to the mute circuit 248 via line 252. The hemodetector circuit is coupled to the mute circuit via line 253. The mode circuit 220 is connected to the status display via line 254. Clamp switch 50 is connected to status display 56 via line 255 and to fail-safe circuit 174 via line 256. The fail-safe relay 242 is connected to clamp magnet 50'via line 258 and mode circuit 220 is connected to clamp circuit 260 via line 261, with the clamp circuit 260 outputting to the status display 56 via line 262 and to clamp magnet 50'via line 263.

In order to understand the operation of rotary switch 48 and how certain operations are inhibited while others are allowed, mode circuit 220, which is schematically illustrated in FIGURES 11a-11b (connected together) will now be described.

Referring to FIGURES 11a-11b, mode signal lines 224-229 from rotary mode switch 48 are fed via resistors 270-275, respectively, and inverters 276-281, respectively, to seven of the eight inputs of a 1 of 8 priority encoder 284. The output 286 of an AND gate 288 is connected to the highest priority input of the priority encoder 284. The load signal line is fed via line 290 to an input of [illegible]

Priority encoder 284 provides a binary output via lines 294, 295 and 296, which are fed thrcugh amplifiers 298, 299 and 300, respectively, to the binary inputs of a PROM 304.

Referring to priority encoder 284, it is noted that the load signal on line 229 has the lowest priority, while the unload signal (which is the combination of the collection complete signal on line 292 and the load signal on line 290) has the highest priority. Encoder 284 takes the highest priority input line and outputs the highest level. In this manner, the various modes are given status levels, in the following order (starting with the lowest status): load, prime, bypass, collect, collection complete, irrigate, reinfuse and unload.

PROM 304 could be a ROM if desired. The output of PROM 304 is held by latch 306, which is clocked every second so that the output of PROM 304 is loaded into latch 306 via lines 307-310 every second. The output of latch 306 is fed back to the input of PROM 304 via lines 312-315. Lines 312-215 also feed the output of latch 306 to inputs of a comparator 320. Comparator 320 compares the binary signal at the input of PROM 304 with a binary signal that is being fed back via lines 312-215. If those binary signals are not equal to each other, an incorrect mode is indicated and the machine is shut off. However, during the brief interval of time that rotary switch 48 is being turned, those binary signals will not be identical and this non-identity will designate an incorrect mode. Output 322 of encoder 284 senses all of the inputs and if there is no signal from any of the inputs, this would signify

fed to OR gate 324 via line 325 and this signal is OR'd with an output signal from comparator 320 fed on line 326. Thus either a signal on line 325 or a signal on line 326 will be fed via OR gate output line 328 to energize a lamp on display 56 which will read "mode switch", as stated above.

PROM 304 is preferably a 256 x 4 PROM which allows 256 possible combinations with respect to the inputs.

The outputs from latch 306 are connected to a second PROM 330 via lines 331-334. PROM 330 is a 32 x 8 PROM and the eight outputs of PROM 330 feed enable signals via lines 336-343. For example, the signal on line 336 is an anticoagulant pump enable signal, the signal on line 337 is a whole blood pump enable signal, the signal on line 338 is a hemolysis detector enable signal, the signal on line 339 is a bubble detector enable signal, the signal on line 340 is a tare/measure select signal, the signal on line 341 is a clamp magnet enable signal, the signal on line 342 is an occluded vein sensor enable signal, and the signal on line 343 is a whole blood pump total volume counter enable signal.

PROM 304 ~~is~~ the PROM (or ROM) which programs whether the particular mode is correct. The second PROM (or ROM) 330 is programmed to determine what should be done when the system is in a valid mode. In other words, if PROM 304 determines that the system is in a proper mode, PROM 330 will determine what should happen as a result of the proper mode (e.g., the enable signals that should be provided). Thus the output signals on lines 336-343 do not actually energize the pumps and other items, but they are enabling

mode is proper, the output of second PROM 330 will enable

the pumps. This will allow the operator to turn the pumps on manually by depressing the pump start switch 70.

Line 328 is connected to line 350 which represents an incorrect mode signal. Line 328 is also connected through inverter 351 and inverter 352 to the mode switch lamp in display 56.

Referring to FIGURE 11a, it is seen that various reset circuits are provided. To this end, a high signal on line 380 will effectively override PROM 304. Thus if a resume switch is pressed, a signal will be fed via line 382 to an input of AND gate 384. A reset signal from line 386 or a reset signal from line 388 simultaneously with a resume signal on line 382 will provide the high signal at the output of AND gate 384 to override PROM (or ROM) 304. Thus, in the event dial switch 48 has been turned to the wrong place and it is important to resume operation of the system instead of having the system completely turned off, by pressing the resume switch PROM 304 can be overridden. In this manner, the operator can turn the dial switch 48 to the mode in which he wants to operate, press the resume switch and the ROM 304 will be overridden so that the particular mode selected will be operating. This resume operation may be useful if the wrong mode has been selected, but it is important that the operator return to the right mode as soon as possible.

The pump start circuit is illustrated in FIGURE 12. Referring to FIGURE 12, it is seen that anti-coagulant pump enable signal line 336 from PROM 330

NAND gate 362. A system armed signal from the clamp (indicating that the clamp is in its unclamped

[illegible] fed via line 364 to the other input of

NAND gate 362. If the tubing clamp is unclamped, a system armed signal will be provided on line 364 and if at the same time a pump enable signal is provided via line 337, the output of NAND gate 362, which is connected to the reset input of flip-flop 366, will indicate that flip-flop 366 should not reset. When flip-flop 366 is reset, Q output 367 is O and since output 367 is connected to an input of AND gate 360, output line 368 of AND gate 360 will be low so that the anticoagulant pump is off. When the reset signal is removed, output 367 remains off until a pump start signal is fed to flip-flop 366 via line 370. The pump start signal on line 370 will turn Q output 367 on and if this occurs simultaneously with a pump enable signal on line 336, the output of AND gate 360 will be high to turn the anticoagulant pump on. However, if the armed signal is lost, such as by clamping the line, a low signal will be fed via line 364 to NAND gate 362, thereby resetting flip-flop 366 and Q output 367 will go to O.

Q output 367 is also connected through an inverter 372 and a resistor 373 to a pump switch signal lamp, preferably in the form of an LED. Q output 367 is also fed via amplifier 374 to turn on the whole blood pump.

It can be seen that one input of AND gate 360 is coupled to output 367 while the other input of AND gate 360 is coupled to the "ACD pump enable" signal, from line 336. There is never a situation in which the operator would want the anticoagulant pump on while the whole blood pump was not on. Thus the anticoagulant pump will be turned on only if both signals from the "whole blo

The mute circuit diagram of FIGURE 13 shows the system for turning off the alarm sound only with respect to the particular alarm condition that is occurring. In other words, if there is an abnormal condition and the alarm sounds, the alarm can be muted so that it no longer sounds. However, if there is another abnormal condition, the alarm will sound notwithstanding the fact that the mute switch has been energized.

The mute switch is coupled via line 400, resistor 402, inverter 404 and clock 406 to the clock input of shift register 408. The alarm signal is fed via line 410 to an input 450 of shift register 408 and the collect plasma signal is fed via line 412 to an AND gate 414. The other input of the AND gate 414 is connected via line 416 to line 227 which carries the bypass mode signal. The output of AND gate 414 is connected to another input 456 of the shift register 408.

An anticipation collection complete signal is fed via line 420 through resistor 421 and inverter 422 to another input 452 of shift register 408 and via line 423 to an input of NAND gate 424. A collection complete signal is fed via line 426 through resistor 427 and amplifier 428 and via line 429 to another input 454 of shift register 408 and to an input of AND gate 430. The output of AND gate 414 is connected via line 432 to an input of AND gate 434 and the signal on line 410 is connected via line 436 to an input of NAND gate 438. The other inputs of NAND gates 438, 424, 430 and 434 are coupled to outputs of the shift register 408.

The outputs of NAND gates 424, 430 and 434 are connected to inputs of another NAND gate 440, the

to an input of NAND gate 443, the output of which provides an audible alarm signal. The output of NAND gate 438 is connected directly to the other input of NAND gate 443.

The mute signal on line 400 will actually be a not mute signal, indicating that the mute switch has not been energized. When the apparatus is started, the system is armed by squeezing the clamp levers. This clears out shift register 408 and effectively puts the outputs of shift register 408 into a first signal mode. The outputs of shift register 408 are fed to inputs of NAND gates 438, 424, 430 and 434 and once reset, shift register 408 outputs provide a high signal at each of the respective inputs to the NAND gates. The other inputs to the NAND gates are the signals from the various alarm conditions, as previously indicated. Thus if one of those signals from an alarm condition also reaches the NAND gate after the shift register has been reset, there will be an audible alarm as indicated in the mute circuit diagram.

The mute switch operates to invert whatever signal is on the input lines and then transfer that signal to the output lines. For example, if shift register 408 was reset so that the outputs were all high's and if the inputs were all low's, if the mute switch was pressed the outputs would be the inverse of the inputs. Thus the mute switch also operates to make the respective output the inverse of its input. If input 450 of shift register 408 had a high signal which indicated an alarm, output 451 of shift register 408 would be low. Likewise, if input 452 was low, then output 453 would be high if the mute switch were pressed. The

particular alarm condition will be shut off.

The mute switch operates only for the particular signals that are at the shift register at the moment that the mute switch is pressed. If after the mute switch is pressed input 454 has a high signal, output 455 will remain high and both inputs of the respective NAND gate 430 will have high signals so that there will be an audible alarm. If the shift register 408 is reset so that all of the outputs 451, 453, 455 and 457 are high, and there is an alarm signal at input 450 and an alarm signal at input 456, normally there would be an audible alarm. However, if the operator wishes to obviate the audible alarm, the mute switch is pressed and output 451 and output 457 have low signals, thereby muting the audible alarm. On the other hand, the alarm would not be muted for alarm signals at input 452 and input 454.

As stated above, the pump circuit is not started unless there is both a "pump enable" signal on line 337 and a "system armed" signal on line 364. In blood processing, it is desirable that the pump be started slowly and to this end, an RC circuit is utilized in a manner so that there is less current to the pump motor while a capacitor is being charged. Thereafter, the pump motor speed is controlled only by the motor speed control potentiometer which is manually controlled by knobs 144 and 146 (FIGURES 1 and 2). The purpose of the initial slow speed with respect to the whole blood pump is to prevent the occlusion of a vein that might result if the blood was drawn rapidly from the beginning.

The pump motor control circuit is illustrated in FIGURE 14. An identical pump motor control is

line 460 through resistor 46[illegible]

transistor 462. In the FIGURE 14 embodiment, the "on" signal is the high while the "off" signal is a low.

When the "on" signal is provided on line 460, transistor 462 will become more conductive and an LED 464, connected in series with the collector of transistor 462, will be energized to provide a more positive voltage at the base of an optically isolated NPN transistor 466. LED 464 and NPN transistor 466 comprise a single unit forming an optical isolator. Once the optical isolator is energized, the voltage is placed across the RC circuit comprising resistor 468 and capacitor 470 so capacitor 470 will charge. At the RC junction 472 there is a diode 474 which is coupled to an input 475 of an operational amplifier 476.

When the power is turned on, there is no voltage across capacitor 470. There is no voltage at input 475 of amplifier 476 and the current is not flowing. The capacitor 470 begins charging and the voltage at the capacitor becomes the voltage at the positive input 475 of amplifier 476. This same voltage appears across resistor 477 at emitter 478 of transistor 480 and that voltage is translated into the output current at collector 481 which is the current to the pump motor.

A potentiomenter 482 is connected to the collector of transistor 466 and input 475 of amplifier 476 is connected through resistor 484 to the wiper arm of potentiometer 482. Thus potentiometer 482 forms the whole blood pump speed control which is operated by manually turning knob 144. The negative input 485 of amplifier 476 is connected to the emitter

in FIGURE 15.

During the operation of the apparatus, certain of the functions are enabled at certain times while others are not enabled at these times. For example, during the "prime" mode, the bubble detector is not enabled because there are bubbles during "prime" and it would present an alarm if the bubble detector were enabled. On FIGURE 15 the lines carrying signals for various functions are illustrated and it can be seen that some of the functions, such as the bubble detector, occluded vein sensor and the hemolysis detector, require enable and operational signals for a malfunction signal to be fed to latch 500. Thus operational signals and enable signals are fed to the inputs of NAND gates 502, 504 and 506, the outputs of which represent, respectively, the bubble detector signal, the occluded vein detector signal and the hemolysis detector signal being fed to latch 500.

Other functions, such as pressure, anticoagulant empty and the fail-safe provisions, are fed directly to latch 500 through inverters 508, 510 and 512, respectively, so that any signals on these lines will operate latch 500. The outputs of latch 500 are fed to the alarm lamps 58 via lines 205, and also to the audible alarm via lines 252.

Latch 500 is an RS latch (reset-set latch) and the function signals are fed to the reset inputs. The reset inputs predominate. If a reset signal is fed to the set input 513 of the latch, because the reset input predominates, the functions will predominate notwithstanding the reset signal at the set input. As long as the condition is present, even if a reset signal is

since inverters 508, 510 and 512 are used, the signals

that will be fed to latch 500 if there is a malfunction will be low signals. Any output from the latch is an alarm signal which shuts down the system and provides audible and lamp signals.

A sensor override switch 74 allows the operator to override some of the alarm signals. Switch 74 is connected to a latch 520 which is coupled to an input of NAND gate 522. Reset switch 76 is also coupled to latch 520 and to the set input of latch 500. Outputs 524, 525 and 526 of latch 500 are coupled to the inputs of NAND gate 528 and outputs 529, 530 and 531 of latch 500 are coupled to the inputs of NAND gate 532. The output of NAND gate 528 is connected to an input of NAND gate 522, the output of which is connected to an input of NAND gate 532. The output of NAND gate 532 is connected to the audible alarm system.

Thus the occluded vein, hemolysis and pressure lines 524, 525 and 526 are fed to NAND gate 528 which is one of the inputs of NAND gate 522, the other of which comes from latch 520 which is controlled by the sensor override switch. Using the sensor override switch 74, the alarm for the occluded vein sensor, hemolysis detector and pressure sensor can be overridden.

The clamp circuit of the present invention is schematically illustrated in FIGURE 16.

Referring to FIGURE 16, it can be seen that clamp switch 50 is connected through an inverter 540 to "return clamped" lamp 542 via line 255. As illustrated in FIGURE 10c, "return clamped" lamp 542 is one of the lamps within display 56.

Clamp switch 50 is also connected to an input

is fed through inverter 540 and via line 54, to the

AND gate 544, magnet enable signal which is fed via line 548 to an input of AND gate 544 and a reset signal which is fed through inverter 549 and via line 550 to an input of AND gate 544. The output of AND gate 544 is coupled through resistor 552 to the base of PNP transistor 554, the emitter of which is grounded and the collector of which is connected to the clamp magnet 50'. Clamp magnet 50' comprises a coil 50a and diode 50b, with an appropriate voltage source coupled thereto. The output of AND gate 544 is also connected via line 556, inverter 557 and line 262 to "system armed" lamp 558 which, as illustrated in FIGURE 10c, forms a portion of the status display 56.

In order to arm the system, the tubing must be unclamped. Once the tubing is unclamped, the system must be in a proper mode to operate. Therefore, AND gate 544 receives the clamp switch signal in addition to an incorrect mode signal which is inverted so it actually becomes a correct mode signal. When all of the signals are present, there will be an output signal from AND gate 544 to turn on transistor 554 so that the clamp magnet 50' will be energized. At the same time, the system armed lamp 558 will become energized.

A fail-safe circuit is provided in order to shut off the system if there is a serious malfunction. The fail-safe circuit is in addition to the alarm circuit and is responsive to the pump speed tachometers, the tubing clamp, the bubble detector and an emergency stop switch (i.e., panic button).

Referring to FIGURE 17, it is seen that the fail-safe circuit includes whole blood pump tachometer signal line 175 and recirculation pump tachometer signal line 178, each of which feeds through a resistor 560,

are clocked by means of a clock 566 which is coupled

through a capacitor 567 and a parallel circuit including resistor 568 and diode 569. The output of counter 564 is fed via line 570 to an input of OR gate 571 while the output of counter 565 is fed via line 572 to another input of OR gate 571.

The clamp signal is fed via line 256 through resistor 574 to an input of OR gate 576. The bubble detector enable signal is fed via line 208 through resistor 573 and inverter 579 to another input of OR gate 576. A second or safety bubble detector signal is fed via line 580 through resistor 581 and inverter 582 to another input of OR gate 576. The output of OR gate 576 is fed to a shift register 584. If there are any inputs at OR gate 576, the output will reset the shift register 584 to provide a zero or low signal via line 585 to OR gate 571.

Counters 564 and 565 are clocked so that if the amount of pulses on either line 175 or line 178 from the tachometer exceeds the count in one second from counter 564 or counter 565, there will be a high signal from one of these counters to OR gate 571. A high signal will then be fed to NOR gate 586 which is coupled with NOR gate 588 as illustrated to form a latch. When NOR gates 586 and 588 latch, a low signal provided through resistor 590 to the base of transistor 592 will provide a relay off signal along line 593 to shut off the entire system.

Likewise, if all inputs are low at OR gate 576, the output will no longer reset shift register 584. After four clock signals from clock 556, shift register 584 will provide a high signal to OR gate 571 thereby providing a signal to latch 586, 588 and the system

and counters 564 and 565 are read every second. If there are more counts going into the counter than its setting, an output signal is provided.

As a specific example, although no limitation is intended, counter 564 is programmed to provide an output signal if the tachometer shows that there is a flow of more than 150 ml per minute. If the tubing has a predetermined diameter, the flow rate is directly proportional to the speed of the tachometer and thus the flow rate can be determined by the tachometer output pulses.

Likewise, counter 565 provides an output signal if there is a flow rate of greater than 600 ml per minute. The outputs of counters 564 and 565 represent 2 to the 12th power and the calibration is such that 2 to the 12th power with counter 564 represents 150 ml per minute while 2 to the 12th power with counter 565 is equivalent to 600 ml per minute. However, the blood is usually flowing from the donor at up to 100 ml per minute and is recirculated to the donor at approximately 300 ml per minute. Shift register 584 serves to provide a four second delay. Thus the condition at the output of OR gate 576 to the reset input of shift register 584 has to be in the low condition for more than four seconds for shift register 584 to provide a high output signal which is inputted to OR gate 571. This delay is needed to prevent nuisance problems from latching the fail-safe circuit.

When NOR gates 586 and 588 latch, signals are provided via line 596 and through resistors 597 and 598, transistors 599 and 600, to a "fail-safe" lamp via line 601 and to an audible alarm device via line 602. The fail-safe lamp is part of the alarm system of display 58.

A "power on" reset circuit is provided including

[illegible] circuit. When the system is initially turned on, the latch 586, 588 is set in an armed mode. When

the latch is armed, any of the events which provide an output from OR gate 571 acts to set the latch by feeding a high signal to NOR gate 586 via line 608.

The relay coupled to line 593 is normally energized if conditions are satisfactory. If there is a disable, the relay is deenergized. The relays are shown in FIGURE 18 which is a block diagram of the fail-safe circuit. It can be seen that the primary power plug 610 is coupled to a suitable source of alternating current and various power supplies and circuits are connected across the alternating current lines 611 and 612. Thus a DC power supply 613 for the logic circuitry is connected in the AC circuit as is the DC power supply 614 for the lamps and fail-safe circuit. In addition, whole blood pump motor control circuit 616 and recirculation pump motor control 618 are coupled across the AC lines.

A first circuit breaker power switch 620 ganged to circuit breaker switch 621 is utilized to open the AC lines. In addition, relay 622 having ganged contacts 623, 624 and 625 is operable in response to the fail-safe circuit of FIGURE 17. When contacts 620, 621 are open, current to the entire system ceases and the apparatus is completely shut off. The opening of contact 624 will deenergize relay 626 to open contact 627 and 628 which provide the alternating current for an auxiliary anticoagulant pump. Opening of contacts 624 will also deenergize clamp magnet 50'.

It can be seen that relay 622 effectively operates off its own DC voltage circuit. Once relay 622 operates to open the line, power to both pumps will be turned off, power to the clamp will be turned off and relay 626 will be deenercized to turn off the

bubbles are detected or the motor speed increases past

a fixed amount, all essential operations of the system will be automatically shut off by the fail-safe circuit.

Although an illustrative embodiment of the invention has been shown and described, it is to be understood that various modifications and substitutions may be made by those skilled in the art without departing from the novel spirit and scope of the present invention.

WHAT IS CLAIMED IS:

1. Blood fractionation apparatus which comprises:

a main housing carrying (a) at least one blood pump, (b) a housing for receiving a disposable blood fractionation filter, (c) electrical control apparatus and (d) means for coupling the housing to a source of electric current;

said main housing having a panel defining a plurality of slots for receiving disposable blood flow tubing within predetermined slots;

said housing carrying sensing means for cooperating with the tubing;

said housing having a manually operable mode switch for setting control functions of the apparatus.

2. Blood fractionation apparatus as described in Claim 1, including programmed means for preventing incorrect actuation of predetermined control functions.

3. Blood fractionation apparatus as described in Claim 2, including means coupling said programmed means to said mode switch, said coupling means providing signals to said programmed means representative of the control function setting of said mode switch.

4. Blood fractionation apparatus as described in Claim 1, including a door member covering at least a portion of said slots to prevent access thereto; means inhibiting operation of said door member and thus access to said slots unless said mode switch is in a predetermined position.

[illegible] disposable filter having [illegible] suitable to separate plasma from the cellular components of the blood, and said housing carrying means

for detecting the presence of the plasma filtrate.

6. Blood fractionation apparatus as described in Claim 1, said housing carrying a safety clamp for clamping the tubing to restrict flow therein; and control means coupled to said safety clamp and to said pump for inhibiting operation of said pump when the tubing is clamped.

7. Blood fractionation apparatus as described in Claim 6, said safety clamp including a pair of members positioned for cooperative magnetic attraction when the safety clamp is in its unclamped position and for separation of the members when the safety clamp is in its clamped position.

8. Blood fractionation apparatus as described in Claim 7, said members comprising a pair of levers that are manually operable to be magnetically attracted when pressed together manually.

9. Blood fractionation apparatus as described in Claim 6, including reset means for inhibiting operation of said pump until both said reset means is actuated and said safety clamp is released to its unclamped position.

10. Blood fractionation apparatus as described in Claim 1, said housing carrying display means for displaying to the operator the present operational mode of the apparatus and selected malfunctions if one or more of such malfunctions occur.

naling a selected malfunction; and operator controlled

means for muting the alarm, said alarm means being operable to enable predetermined functions during selected modes while other functions are inhibited.

12. Blood fractionation apparatus as described in Claim 11, including means for overriding said alarm means for predetermined functions.

13. Blood fractionation apparatus as described in Claim 1, whereby said housing further carries an anticoagulant pump and includes means for carrying a supply of anticoagulant; means inhibiting operation of said anticoagulant pump until said blood pump is enabled.

14. Blood fractionation apparatus as described in Claim 13, including means for sensing the presence of anticoagulant; and means responsive to said sensing means for inhibiting the operation of the pump if no anticoagulant is sensed.

15. Blood fractionation apparatus as described in Claim 6, including a fail-safe circuit coupled to said safety clamp, bubble detector and pump; said fail-safe circuit including delay means and means for terminating operation of the apparatus in response to a predetermined signal from one of said safety clamp, bubble detector and pump after a predetermined delay from receipt of said predetermined signal.

16. Blood fractionation apparatus as described in Claim 15, said fail-safe circuit including first means responsive to pump speed for providing an over-

a bubble detected signal; said first, second and third means being coupled to inputs of an OR gate; a delay circuit coupled to the output of said OR gate; and switch means coupled to the output of said delay circuit for terminating operation of the apparatus in response to a predetermined output signal.

17. Blood fractionation apparatus which comprises:

a main housing carrying (a) at least one blood pump, (b) a housing for receiving a disposable blood fractionation filter, (c) electrical circuit apparatus and (d) means for coupling the housing to a source of electric current;

said main housing having a panel defining a plurality of slots for receiving disposable blood flow tubing within predetermined slots;

a door member covering at least a portion of said slots to prevent access thereto;

said disposable filter having a membrane suitable to separate plasma from the cellular components, and said housing carrying means for detecting the presence of plasma filtrate;

said housing carrying sensing means for cooperation with the tubing;

said housing having a manually operable mode switch for setting control functions of the apparatus;

means inhibiting operation of said door member and thus access to said slots unless said mode switch is in a predetermined position; and

programmed means for preventing incorrect actuation of predetermined control functions, means coupling said programmed means to said mode switch, said coupling means providing signals to said pro-

18. Blood fractionation apparatus which comprises:

a main housing carrying (a) at least one blood pump, (b) a housing for receiving a disposable blood fractionation filter, (c) electrical control apparatus and (d) means for coupling the housing to a source of electrical current;

said main housing having a panel defining a plurality of slots for receiving disposable blood flow tubing within predetermined slots;

a door member covering at least a portion of said slots to prevent access thereto;

said disposable filter having a membrane suitable to separate plasma from the cellular components, and said housing carrying means for detecting the presence of plasma filtrate;

said housing having a manually operable mode switch for setting control functions of the apparatus;

means inhibiting operation of said door member and thus access to said slots unless said mode switch is in a predetermined position;

said housing carrying a safety clamp for clamping the tubing to restrict flow therein;

control means coupled to said safety clamp and to said pump for inhibiting operation of said pump when the tubing is clamped;

said safety clamp including a pair of members positioned for cooperative magnetic attraction when the safety clamp is in its unclamped position and for separation of the members when the safety clamp is in its clamped position;

said members comprising a pair of levers that are manually operable to be magnetically attracted

pump until both said reset means is actuated and said

safety clamp is released to its unclamped position.

19. Blood fractionation apparatus as described in Claim 18, including programmed means for preventing incorrect actuation of predetermined control functions, and means coupling said programmed means to said mode switch, said coupling means providing signals to said programmed means representative of the control function setting of said mode switch.

20. Blood fractionation apparatus which comprises:

a main housing carrying (a) at least one blood pump, (b) electrical control apparatus and (c) means for coupling the housing to a source of electric current;

said housing having a manually operable mode switch for setting control functions of the apparatus;

programmed means for preventing incorrect actuation of predetermined control functions;

means coupling said programmed means to said mode switch, said coupling means providing signals to said programmed means representative of the control function setting of said mode switch.

21. Blood fractionation apparatus as described in Claim 20, said housing carrying a safety clamp for clamping the tubing to restrict flow therein; and control means coupled to said safety clamp and to said pump for inhibiting operation of said pump when the tubing is clamped.

22. Blood fractionation apparatus as described

and for separation of the members when the safety

clamp is in its clamped position.

23. Blood fractionation apparatus as described in Claim 22, said members comprising a pair of levers that are manually operable to be magnetically attracted when pressed together manually.

24. Blood fractionation apparatus as described in Claim 21, including reset means for inhibiting operation of said pump until both said reset means is actuated and said safety clamp is released to its unclamped position.

25. Blood fractionation apparatus as described in Claim 20, said housing carrying display means for displaying to the operator the present operational mode of the apparatus and selected malfunctions if one or more of such malfunctions occur.

26. Blood fractionation apparatus as described in Claim 25, including audible alarm means for signaling a selected malfunction; and operator controlled means for muting the alarm, said alarm means being operable to enable predetermined functions during selected modes while other functions are inhibited.

27. Blood fractionation apparatus as described in Claim 26, including means for overriding said alarm means for predetermined functions.

28. Blood fractionation apparatus as described in Claim 21, said housing carrying an occluded vein

pressure in the tubing; and a fail-safe circuit coupled to said safety clamp, bubble detector and

pump; said fail-safe circuit including delay means and means for terminating operation of the apparatus in response to a predetermined signal from one of said signal clamp, bubble detector and pump after a predetermined delay from receipt of said predetermined signal.

29. Blood fractionation apparatus as described in Claim 28, said fail-safe circuit including first means responsive to pump speed for providing an overspeed signal, second means responsive to the safety clamp operation for providing a clamp signal and third means responsive to the bubble detector for providing a bubble detected signal; said first, second and third means being coupled to inputs of an OR gate; a delay circuit coupled to the output of said OR gate; and switch means coupled to the output of said delay circuit for terminating operation of the apparatus in response to a predetermined output signal.

30. Blood fractionation apparatus which comprises:

a main housing carrying (a) at least one blood pump, (b) electrical control apparatus and (c) means for coupling the housing to a source of electric current;

said housing carrying a bubble detector for cooperation with blood tubing, and pressure sensing means for sensing blood pressure;

said housing having a manually operable mode switch for setting control functions of the apparatus;

said housing carrying a safety clamp for clamping the tubing to restrict flow therein;

pump when the tubing is clamped;

said housing carrying display means for

displaying to the operator the present operational mode of the apparatus and selected malfunctions if one or more of such malfunctions occur;

audible alarm means for signaling a selected malfunction;

operator controlled means for muting the alarm, said alarm means being operable to enable predetermined functions during selected modes while other functions are inhibited; and

a fail-safe circuit coupled to said safety clamp, bubble detector and pump; said fail-safe circuit including delay means and means for terminating operation of the apparatus in response to a predetermined signal from one of said safety clamp, bubble detector and pump after a predeterminded delay from receipt of said predetermined signal.

31. Blood fractionation apparatus which comprises:

a main housing carrying a blood pump, means for separating blood components, electrical control apparatus and means for coupling the housing to a source of electric current;

said housing having means coupled to said electrical control apparatus for setting control functions of the apparatus;

said control functions comprising a plurality of operational modes and said electrical control apparatus including means for providing a signal representing each mode, means for encoding said mode signals to output a highest priority signal only, a comparator, programmed memory means for storing proper

means for feeding the encoded mode signal to said comparator, means for feeding the memory means output

to the comparator, said comparator being operable to compare the encoded mode signal with the memory means output; and means coupled to the output of the comparator for providing (a) a first signal if there is a first relationship between the encoded mode signal and the memory means output, and (b) a second signal if there is a second relationship between the encoded mode signal and the memory means output.

32. Blood fractionation apparatus as described in Claim 31, said first relationship comprising an encoded mode signal that is identical to the memory means output signal; and said second relationship comprising an encoded mode signal that is not identical to the memory means output signal.

33. Blood fractionation apparatus as described in Claim 32, said encoded mode signal comprising a binary signal.

34. Blood fractionation apparatus as described in Claim 32, said second signal being operable to terminate operation of the appparatus; and including means for inhibiting such termination if there is no mode signal.

35. Blood fractionation apparatus as described in Claim 31, including second programmed memory means for storing data for enabling operation of equipment carried by said housing; means coupling said second programmed memory means to the output of said first-mentioned programmed memory means, whereby an enabling signal may be provided by said second programmed mem-

36. Blood fractionation apparatus which comprises:

a main housing carrying a blood pump, means for separating blood components, electrical control apparatus and means for coupling the housing to a source of electric current;

said housing having means coupled to said electrical control apparatus for setting control functions of the apparatus;

said control functions comprising a plurality of operational modes and said electrical control apparatus including means for providing a signal representing each mode, means for encoding said mode signals to output a highest priority signal only, a comparator, first programmed memory means for storing proper mode sequence data, means for feeding the encoded mode signal to an input of said programmed memory means, means for feeding the encoded mode signal to said comparator, means for feeding the memory means output to the comparator, said comparator being operable to compare the encoded mode signal with the memory means output; means for providing (a) a first signal if there is an encoded mode signal that is identical to the memory means output signal, and (b) a second signal if there is an encoded mode signal that is not identical to the memory means output signal;

said encoded mode signals comprising binary signals;

said second signal being operable to terminate operation of the apparatus, and including means for inhibiting such termination if there is no mode signal;

second programmed memory means for storing data for enabling operation of equipment carried by

means to the output of said first programmed memory means, whereby an enabling signal may be provided by said second programmed memory means if a proper sequence mode signal is provided.

37. Control apparatus for controlling the operation of apparatus in which a proper mode sequence is required, comprising:

mode switch means;

means for providing a signal representing each mode;

means for encoding said mode signals to output a highest priority signal only;

a comparator;

first programmed memory means for storing proper mode sequence data;

means for feeding the encoded mode signal to an input of said first programmed memory means;

means for feeding the encoded mode signal to said comparator;

means for feeding the memory means output to the comparator;

said comparator being operable to compare the encoded mode signal with the memory means output; and

means coupled to the output of said comparator for providing (a) a first signal if there is a first relationship between the encoded mode signal and the memory means output, and (b) a second signal if there is a second relationship between the encoded mode signal and the memory means output.

38. Control apparatus as described in Claim 37,

encoded mode signal that is not identical to the memory means output signal.

39. Control apparatus as described in Claim 38, said encoded mode signal comprising a binary signal.

40. Control apparatus as described in Claim 38, said second signal being operable to terminate operation of the apparatus; and including means for inhibiting such termination if there is no mode signal.

41. Control apparatus as described in Claim 37, including second programmed memory means for storing data for enabling operation of selected equipment; means coupling said second programmed memory means to the output of said first programmed memory means, whereby an enabling signal may be provided by said second programmed memory means if a proper sequence mode signal is provided.

42. Control apparatus for controlling the operation of apparatus in which a proper mode sequence is required, comprising:

mode switch means;

means for providing a signal representing each mode;

means for encoding said mode signals to output a highest priority signal only;

a comparator;

first programmed memory means for storing proper mode sequence data;

means for feeding the encoded mode signal to an input of said programmed memory means;

means for feeding the encoded mode signal to said comparator;

means for feeding the memory means output to the comparator;

said comparator being operable to compare the encoded mode signal with the memory means output;

means coupled to the output of the comparator for providing (a) a first signal if there is an encoded mode signal that is identical to the memory means output signal, and (b) a second signal if there is an encoded mode signal that is not identical to the memory means output signal;

said encoded mode signal comprising a binary signal;

said second signal being operable to terminate operation of the apparatus, and including means for inhibiting such termination if there is no mode signal;

second programmed memory means for storing data for enabling operation of selected equipment;

means coupling said second programmed memory means

[illegible]

is provided.

43. Blood fractionation apparatus which comprises:

a main housing carrying (a) at least one blood pump, (b) a housing for receiving a disposable blood fractionation filter, (c) electrical control apparatus and (d) means for coupling the housing to a source of electric current;

a manually operable mode switch coupled to said control apparatus for setting control functions of the apparatus;

said control functions including a load mode enabling the fractionation apparatus to be loaded with disposable tubing, a prime mode for priming the system with a selected liquid, a start mode for withdrawing whole blood from a donor and passing the whole blood through the filter but returning all blood components to the donor, and a collect mode for collecting one of the separated components while returning other blood components to the donor.

44. Blood fractionation apparatus as described in Claim 43, said control functions further including an irrigate mode in which the apparatus is not functioning to collect one of the separated components but a selected solution is provided to maintain venal punctures open and the tubing clean.

45. Blood fractionation apparatus as described in Claim 44, said control functions further including a reinfuse mode in which said other blood components within the tubing are reinfused to the donor after said one of the separated components is collected.

preventing incorrect sequence of predetermined control functions.

47. Blood fractionation apparatus as described in Claim 46, said control apparatus comprising means for overriding said incorrect sequence preventing means.

48. Apparatus for membrane plasmapheresis which comprises:

a main housing carrying (a) at least one blood pump, (b) a housing for receiving a blood plasma filter, (c) electrical control apparatus and (d) means for coupling the housing to a source of electric current;

a manually operable mode switch coupled to said control apparatus for setting control functions of the apparatus;

said control functions including a load mode enabling the plasmapheresis apparatus to be loaded with disposable tubing, a prime mode for priming the system with saline solution, a start mode for withdrawing whole blood from the donor and passing the whole blood through the filter but returning all blood components to the donor, a collect mode for collecting plasma while returning other blood components to the donor, an irrigate mode in which the plasmapheresis apparatus is not functioning to collect the plasma but a saline solution is provided to maintain venal punctures open and the tubing clean, a reinfuse mode in which red blood cells within the tubing are reinfused to the donor after the plasma is collected; and

said control apparatus comprising means for preventing incorrect sequence of predetermined control functions.

49. Blood fractionation apparatus, which comprises:

a whole blood pump;

a recirculation pump;

speed control means coupled to said whole blood pump and recirculation pump;

blood flow tubing;

means for sensing (a) the whole blood pump rate, (b) the recirculation pump rate, (c) blood pressure, (d) amount of blood component that is collected and (e) air bubbles in the tubing;

display means for displaying predetermined control functions;

an alarm circuit for providing an audible alarm resulting from the sensing of predetermined conditions; and

safety clamping means for clamping the tubing under predetermined conditions.

50. Blood fractionation apparatus as described in Claim 49, including means for sensing the presence of an occluded vein condition and means responsive to predetermined sensed conditions for terminating operation of the apparatus.

51. Blood fractionation apparatus as described in Claim 49, including a filter membrane for separation of plasma from the cellular components, and means for detecting the presence of plasma filtrate.

52. Blood fractionation apparatus as described in Claim 49, including means coupled to said safety clamp

53. Blood fractionation apparatus as described in Claim 52, said safety clamp including a pair of members positioned for cooperative magnetic attraction when the safety clamp is in its unclamped position and for separation of the members when the safety clamp is in its clamped position.

54. Blood fractionation apparatus as described in Claim 53, said members comprising a pair of levers that are manually operable to be magnetically attracted when pressed together manually.

55. Blood fractionation apparatus as described in Claim 49, including operator controlled means for muting the audible alarm, said alarm circuit being operable to enable predetermined functions during selected modes while other functions are inhibited.

56. Blood fractionation apparatus as described in Claim 49, including a fail-safe circuit coupled to said safety clamping means, air bubble sensing means and pumps, said fail-safe circuit including delay means and means for terminating operation of the apparatus in response to a predetermined signal from one of said clamping means, air bubble sensing means and pumps after a predetermined delay from receipt of said predetermined signal.

57. Blood fractionation apparatus as described in Claim 56, said fail-safe circuit including first means responsive to the blood pump speed for providing an overspeed signal, second means responsive to the recirculation pump speed for providing an overspeed signal, third means responsive to the safety clamp operation for providing a clamp signal, said first, second and third means being coupled to inputs of an OR gate, a delay circuit coupled to the output of said OR gate, and switch means coupled to the output of said delay circuit for terminating operation of the apparatus in response to a predetermined output signal.

58. Blood fractionation apparatus which comprises:

a whole blood pump;

a recirculation pump;

speed control means coupled to said whole blood pump and recirculation pump;

blood flow tubing;

means for sensing (a) the whole blood pump rate, (b) the recirculation pump rate, (c) blood pressure, (d) amount of blood component that is collected, and (e) air bubbles in the tubing;

display means for displaying predetermined control functions;

an alarm circuit for providing an audible alarm resulting from the sensing of predetermined conditions;

safety clamping means for clamping the tubing under predetermined conditions;

means for sensing the presence of an occluded vein condition and means responsive to predetermined sensed conditions for terminating operation of the apparatus;

[illegible] means for detecting the presence of plasma filtrate;

means coupled to said safety clamp means and to said pumps for inhibiting operation of said pumps when the tubing is clamped;

operator controlled means for muting the audible alarm, said alarm circuit being operable to enable predetermined functions during selected modes while other functions are inhibited; and

a fail-safe circuit coupled to said safety clamping means, air bubble sensing means and pumps, said fail-safe circuit including delay means and means for terminating operation of the apparatus in response to a predetermined signal from one of said safety clamping means, air bubble sensing means and pumps after a predetermined delay from receipt of said predetermined signal.

59. Blood fractionation apparatus which comprises:

a main housing carrying (a) at least one blood pump, (b) a housing for receiving a disposable blood fractionation filter, (c) electrical control apparatus and (d) means for coupling the housing to a source of electric current;

means for sensing a plurality of predetermined control functions;

means coupling said sensing means to said electrical control apparatus;

means coupling said electrical control apparatus to output displays;

a fail-safe circuit;

means coupling only selected ones of said predetermined control functions sensing means to said fail-safe circuit;

an alarm circuit;

means coupling said fail-safe circuit output to said alarm circuit;

means coupling other selected ones of said predetermined control functions sensing means to said alarm circuit;

a manually operable mode switch for setting control functions of the apparatus; and

means coupling said mode switch to said alarm circuit.

60. Blood fractionation apparatus as described in Claim 59, said predetermined control functions including blood pump speed, blood pressure, bubble detection, occluded vein detection, and separated component presence detection.

61. Blood fractionation apparatus as described in Claim 60, including programmed means for preventing incorrect actuation of predetermined control functions, means coupling said programmed means to said mode switch, said coupling means providing signals to said programmed means representative of the control function setting of the manually operable mode switch.

62. Blood fractionation apparatus as described in Claim 60, including audible alarm means for signaling a selected malfunction, and operator controlled means for muting the alarm, said alarm means being operable to enable predetermined functions during selected modes while other functions are inhibited.

63. Blood fractionation apparatus as described in Claim 60, and further including an anticoagulant pump and means for carrying a supply of anticoagulant; and means inhibiting operation of said anticoagulant pump until said blood pump is enabled.

64. Blood fractionation apparatus as described in Claim 63, including means for sensing the presence of anticoagulant; and means responsive to said sensing means for inhibiting the operation of the pumps if no anticoagulant is sensed.

65. Blood fractionation apparatus which comprises:

a main housing carrying (a) at least one blood pump, (b) a housing for receiving a disposable blood fractionation filter, (c) electrical control apparatus and (d) means for coupling the housing to a source of electric current;

means for sensing a plurality of predetermined control functions;

means coupling said sensing means to said electrical control apparatus;

means coupling said electrical control apparatus to output displays;

a fail-safe circuit;

means coupling only selected ones of said predetermined control functions sensing means to the fail-safe circuit;

an alarm circuit;

means coupling said fail-safe circuit output to said alarm circuit;

means coupling other selected ones of said predetermined control functions sensing means to said alarm circuit;

a manually operable mode switch for setting control functions of the apparatus;

means coupling said mode switch to said alarm circuit;

said predetermined control functions including blood pump speed, blood pressure, bubble detection, occluded vein detection, and separated component presence detection;

programmed means for preventing incorrect actuation of predetermined control functions, means coupling said programmed means to said mode switch, said coupling means

audible alarm means for signaling a selected malfunction and operator controlled means for muting the alarm, said alarm means being operable to enable predetermined functions during selected modes while other functions are inhibited;

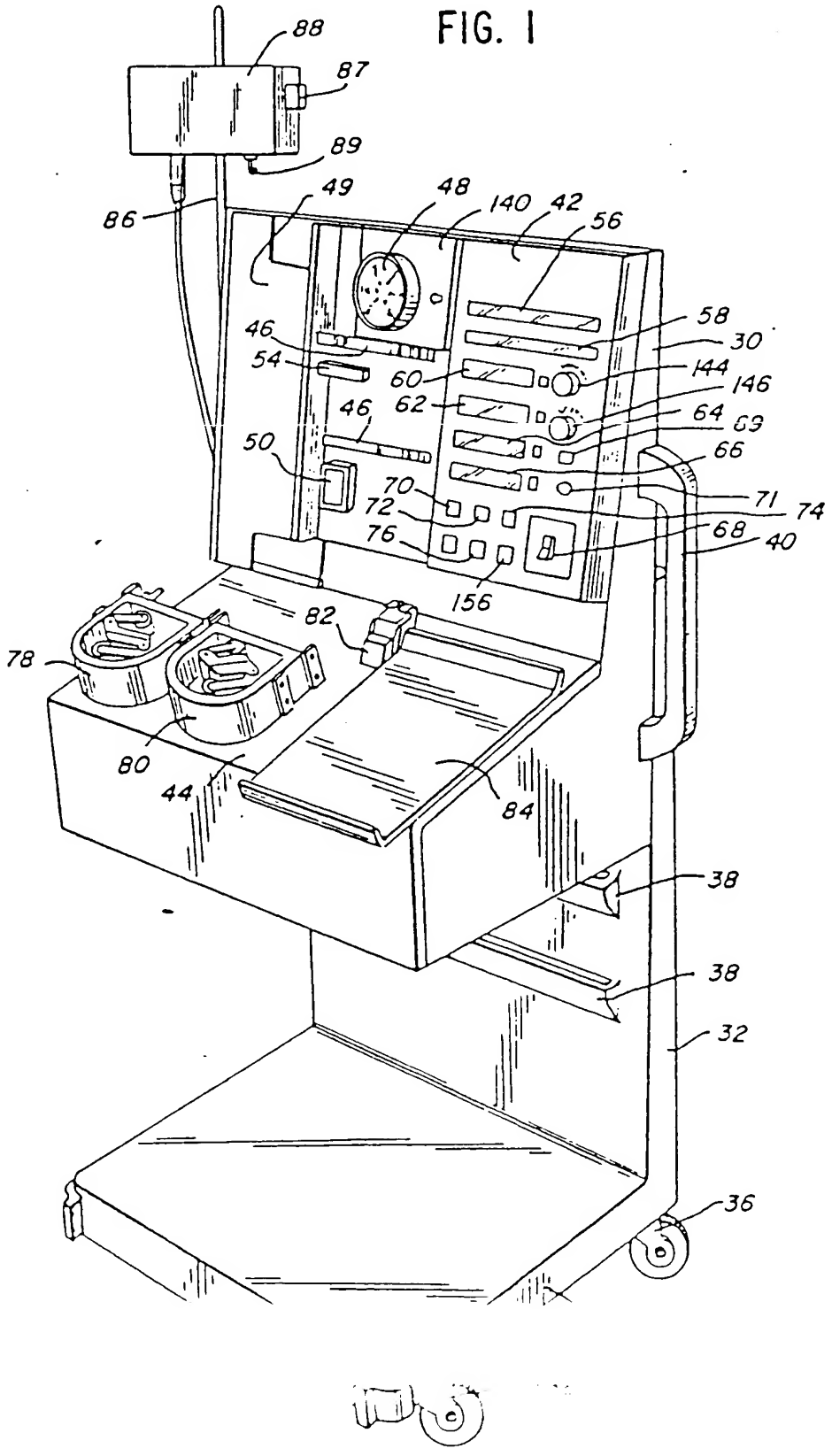
an anticoagulant pump and means for carrying a supply of anticoagulant;

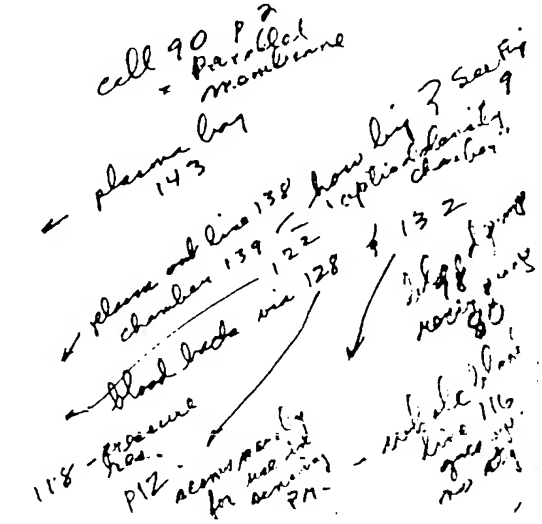
means inhibiting operation of said anticoagulant pump until said blood pump is enabled;

means for sensing the presence of anticoagulant; and

means responsive to said sensing means for inhibiting the operation of the pumps if no anticoagulant is sensed.

FIG. 1

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PIZ -
PI -

FIG. 2

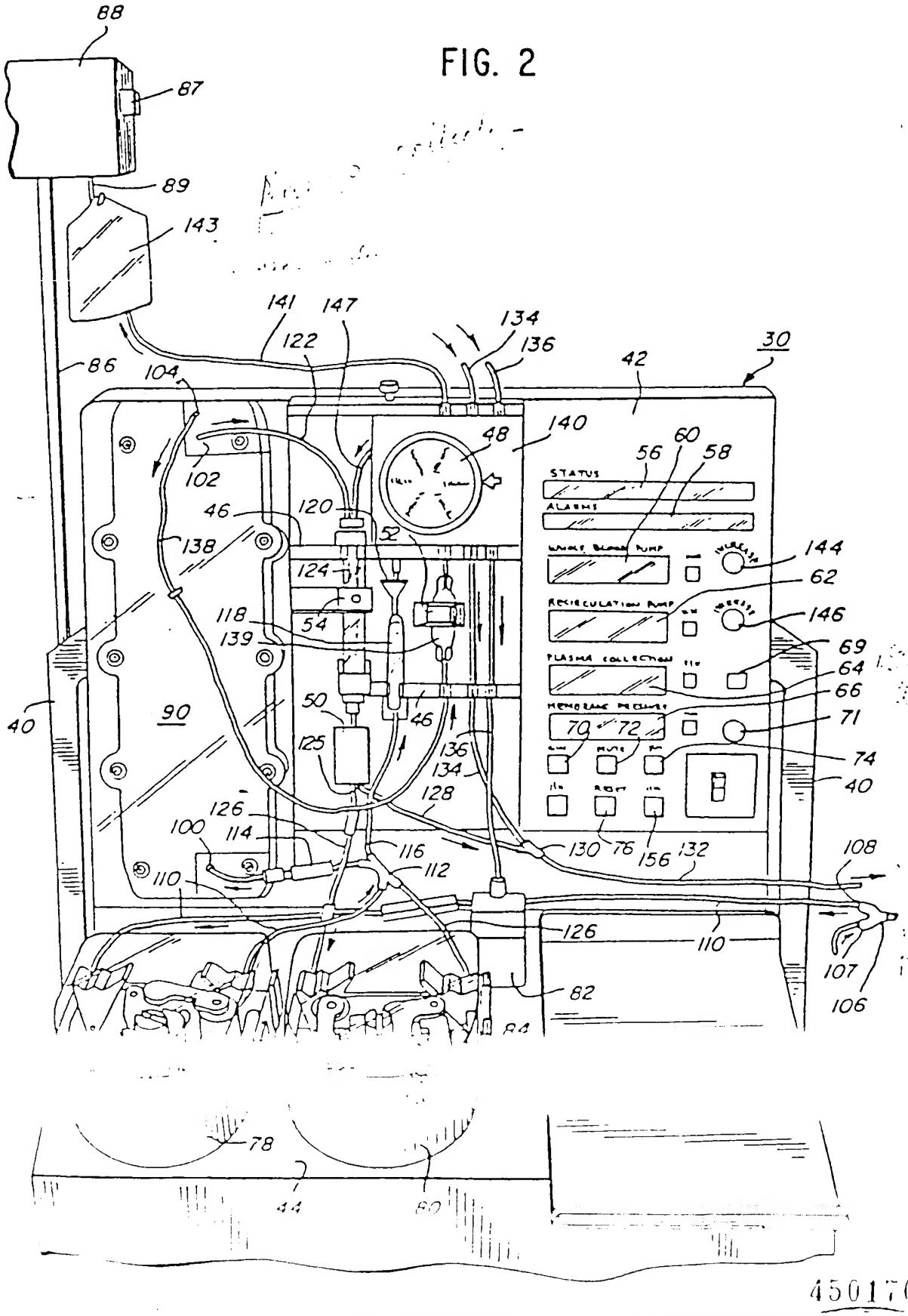
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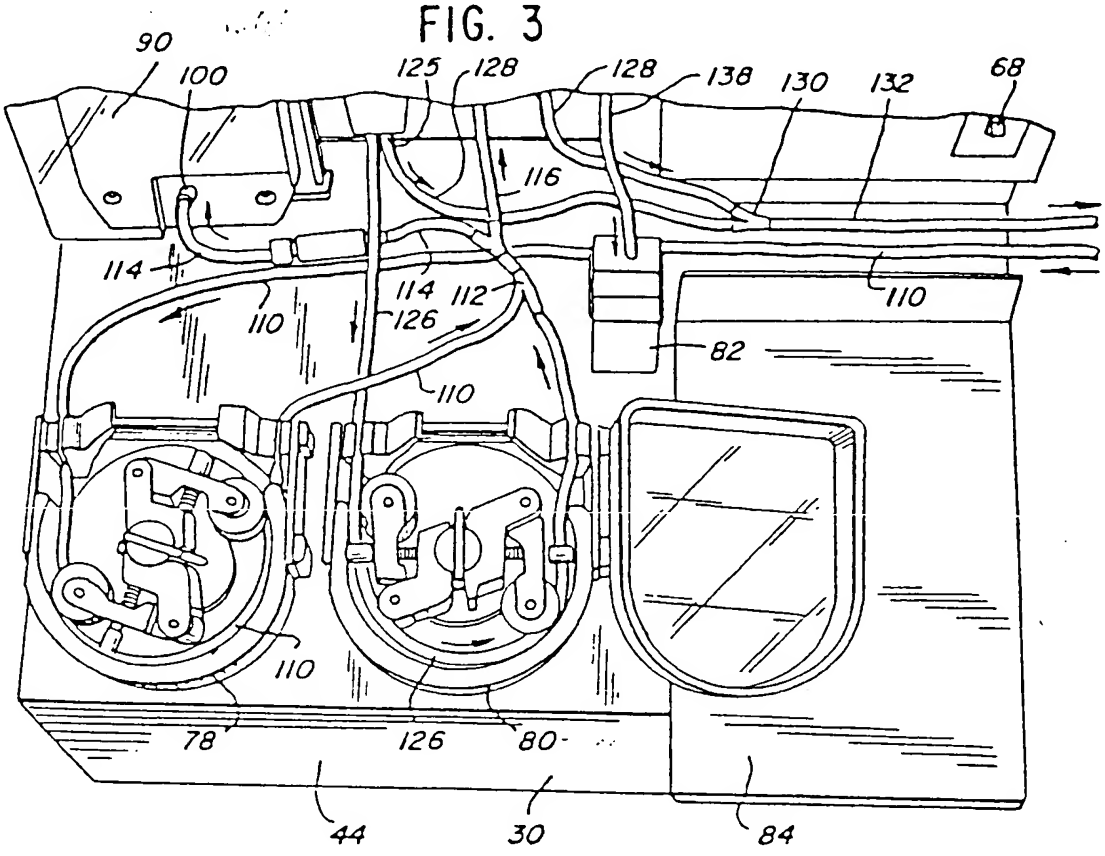
FIG. 3



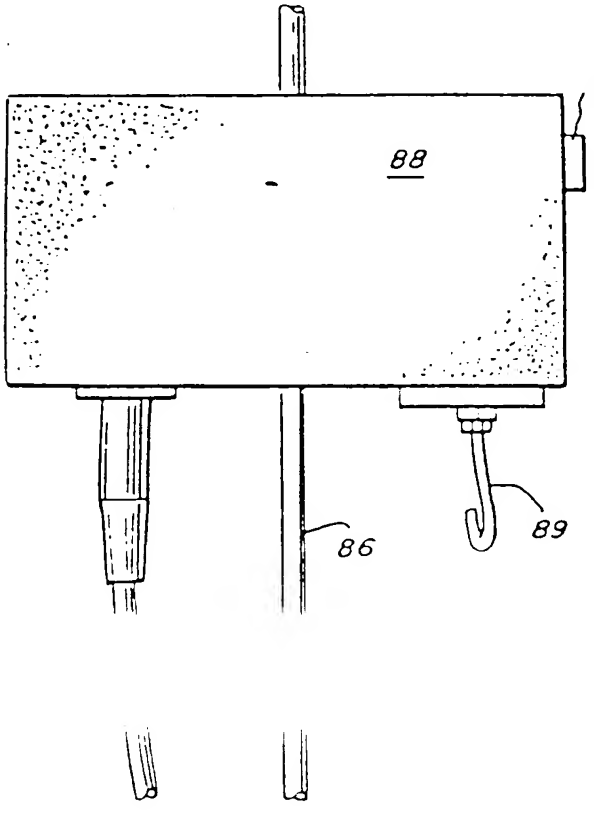
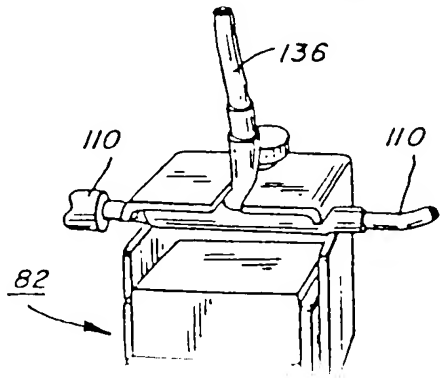


FIG. 4

FIG. 5



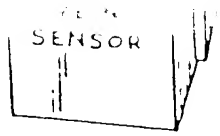


FIG. 6

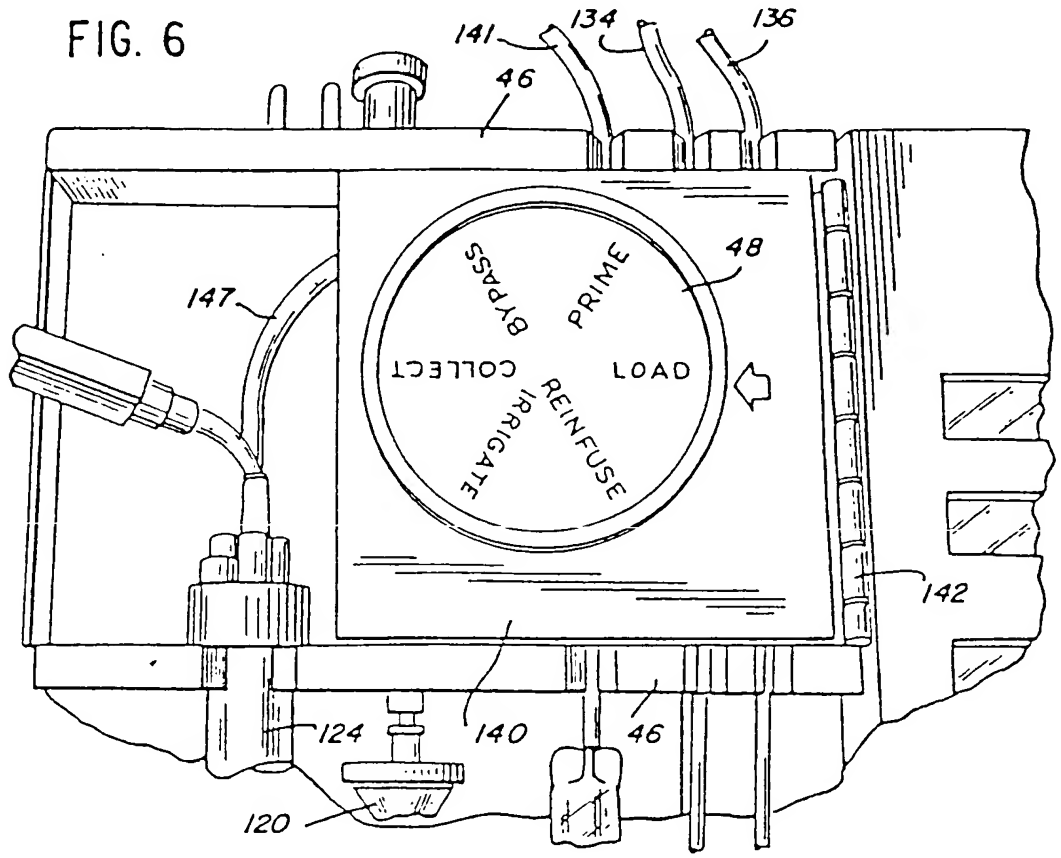
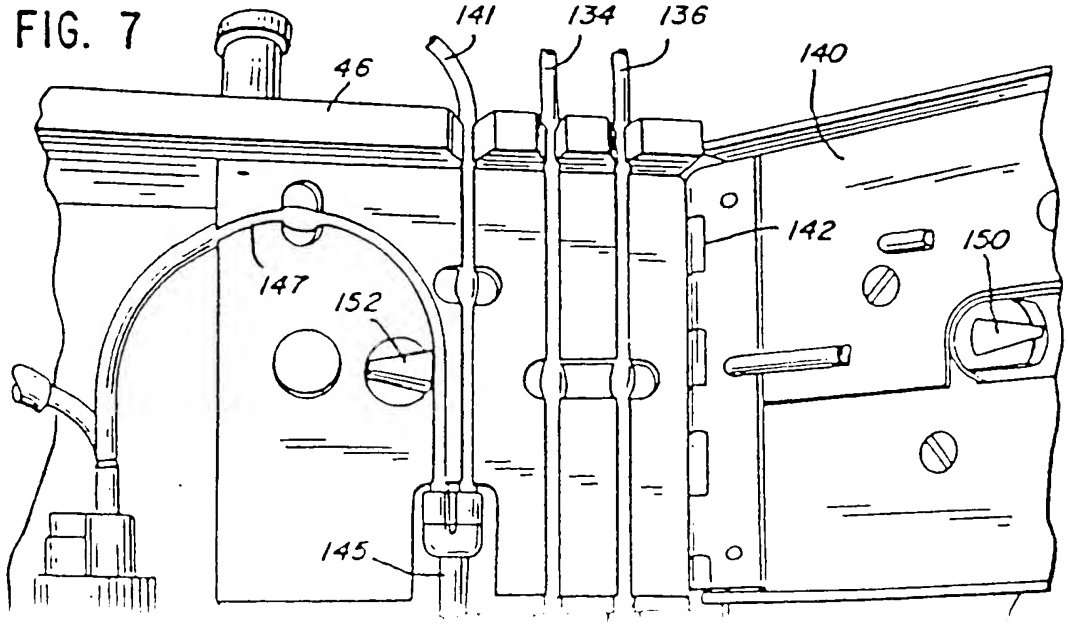


FIG. 7



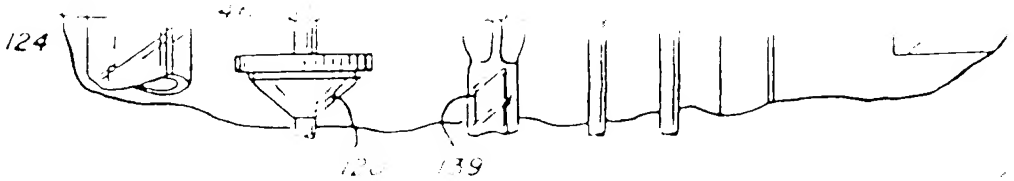


FIG. 8

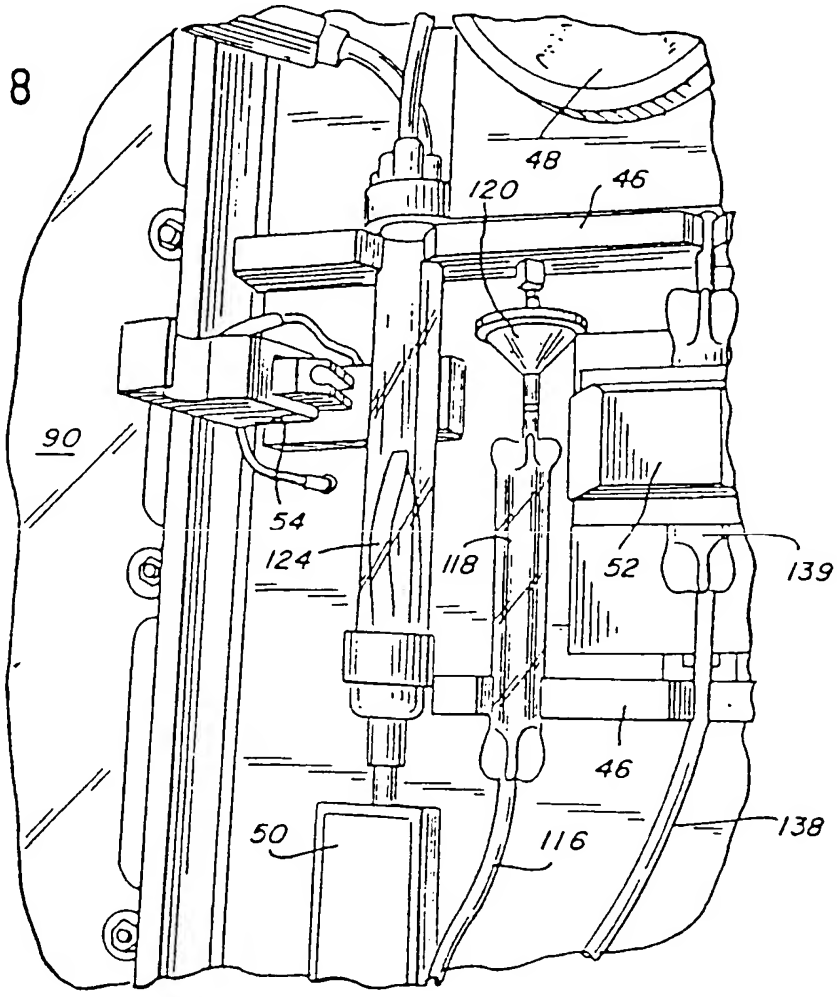
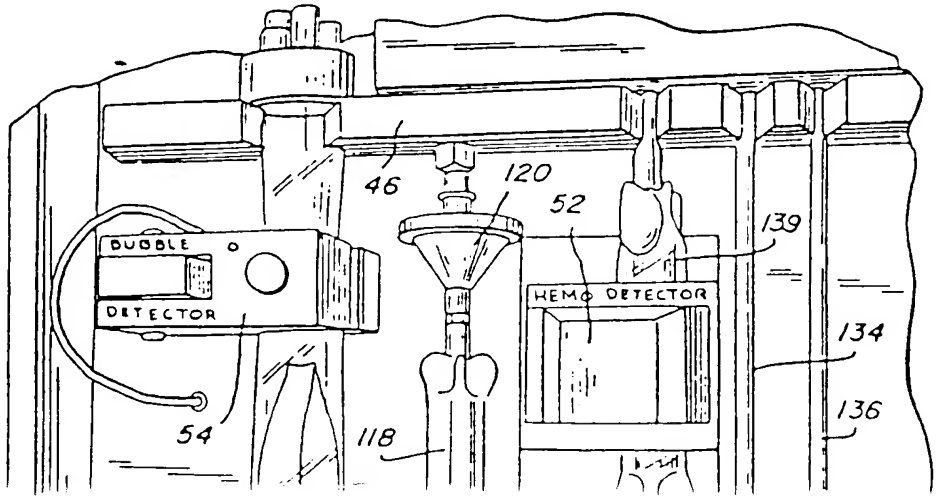
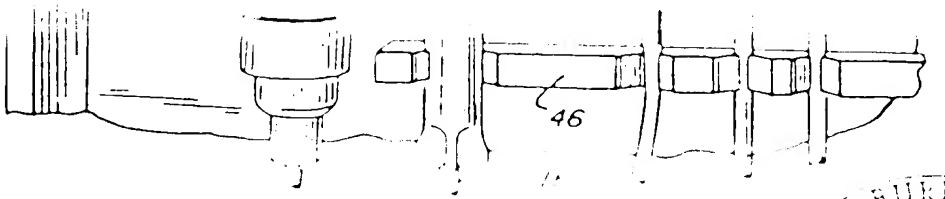


FIG. 9





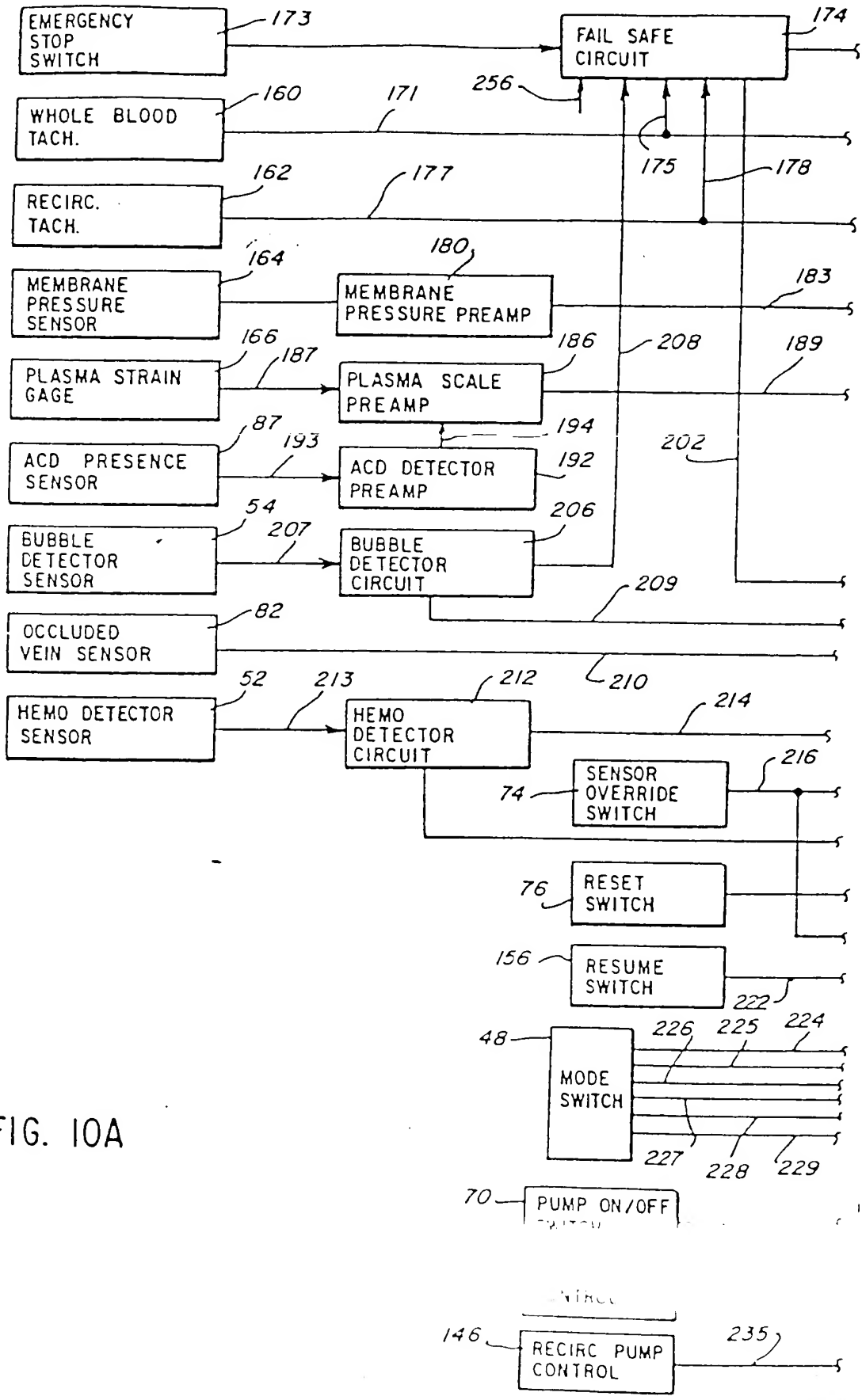


FIG. 10A

FIG. 10B

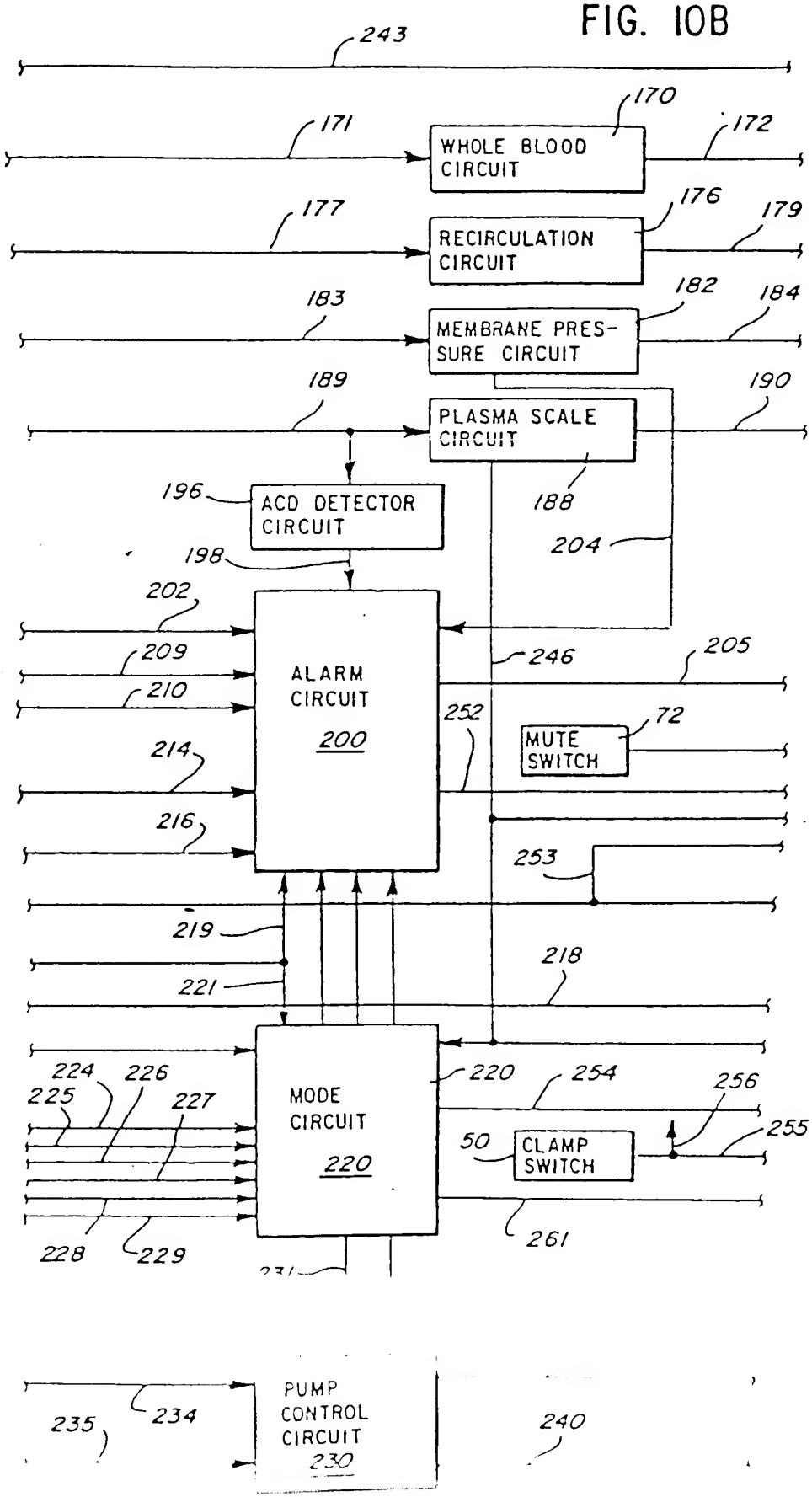
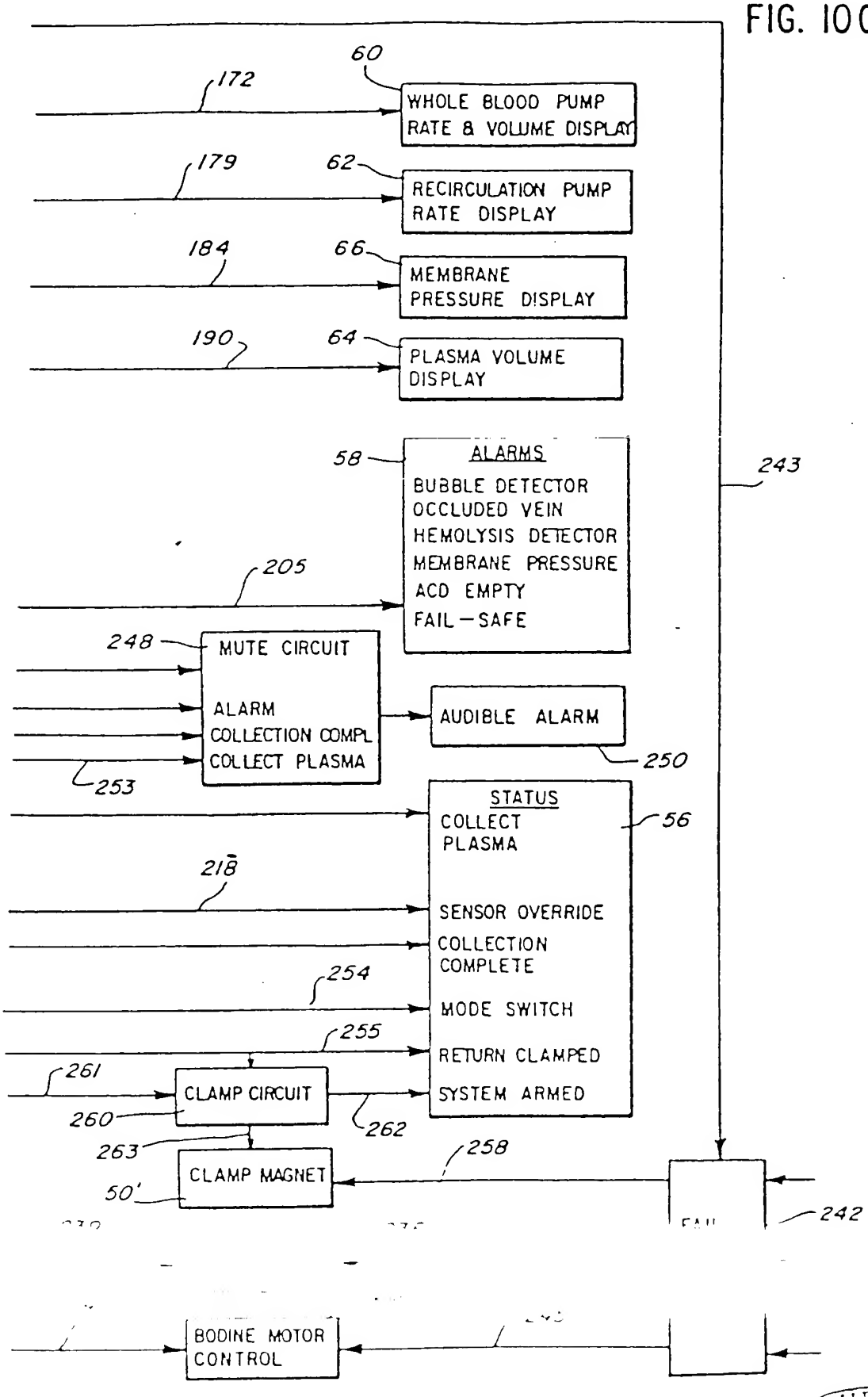


FIG. 10C



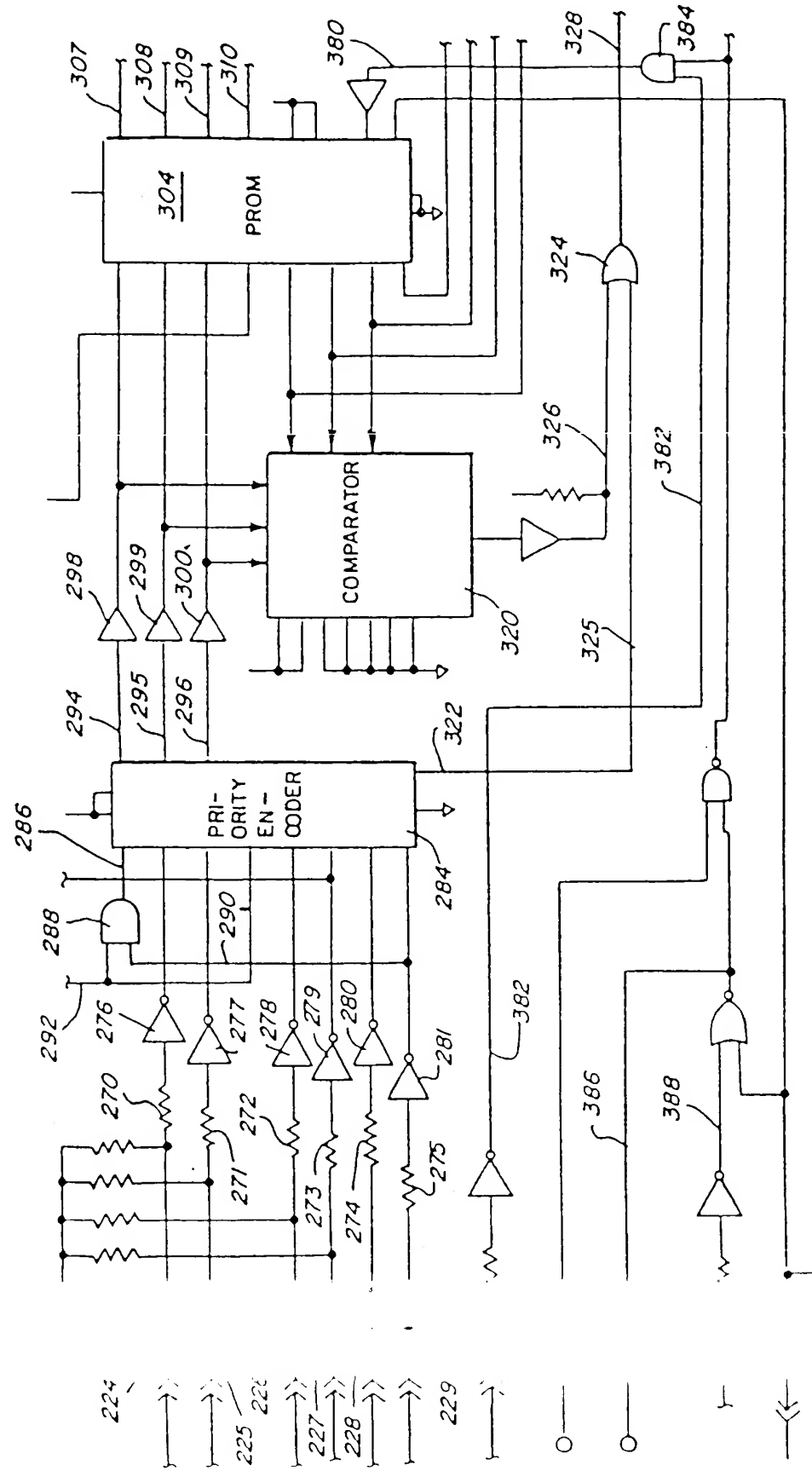


FIG. IIA

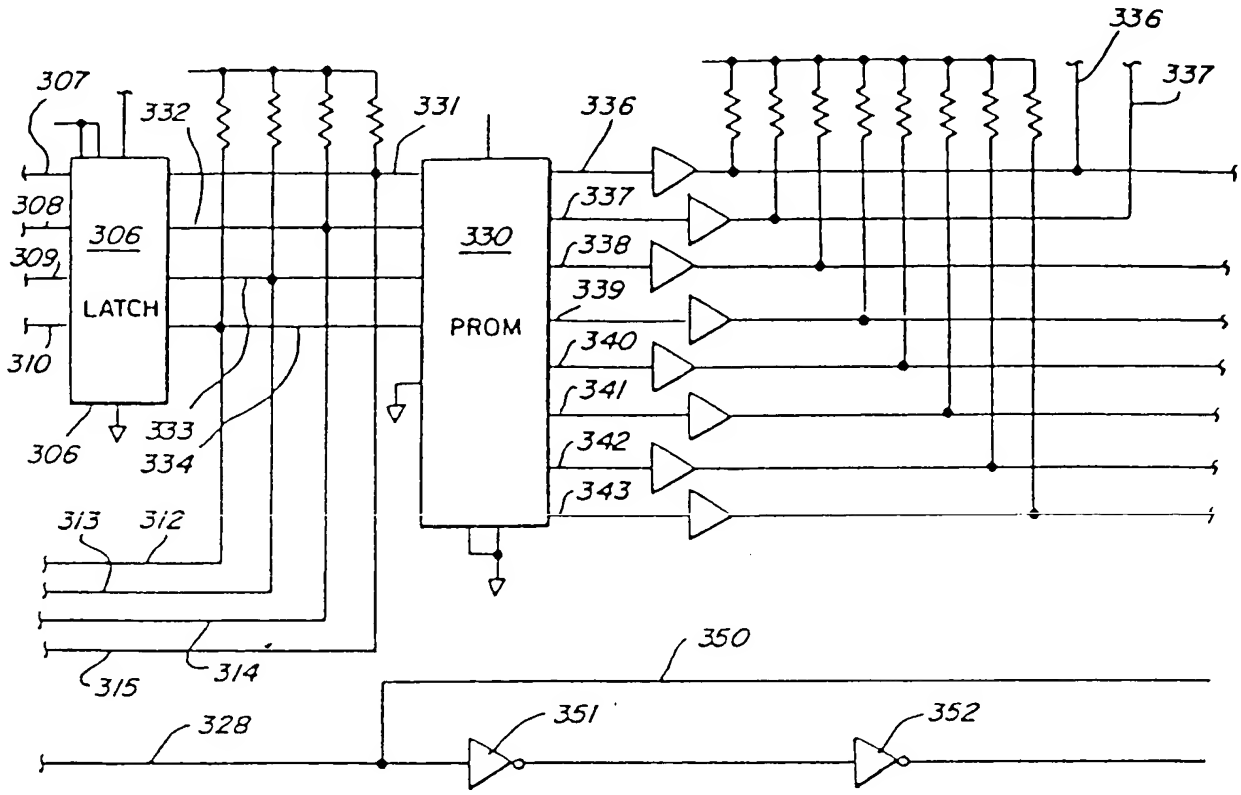


FIG. 11B

FIG. 12

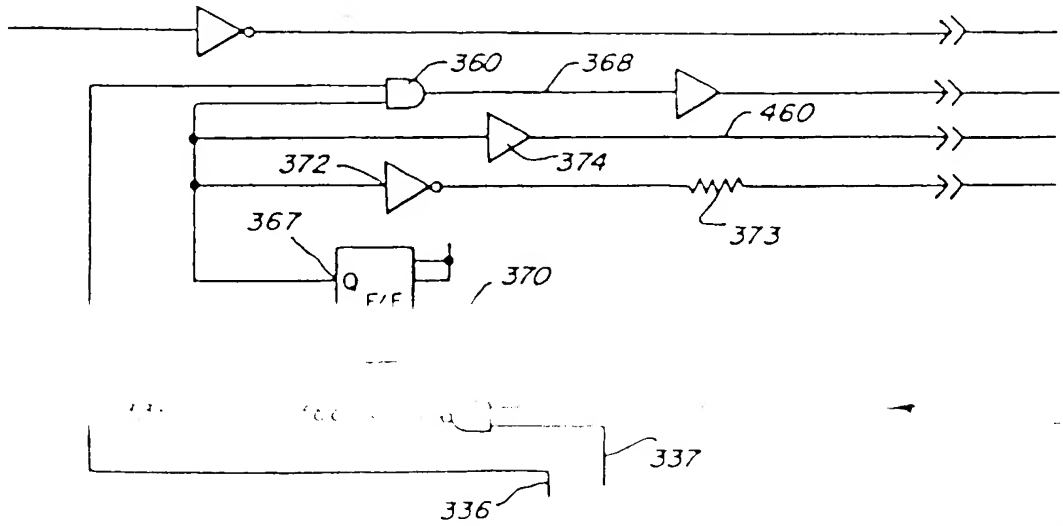
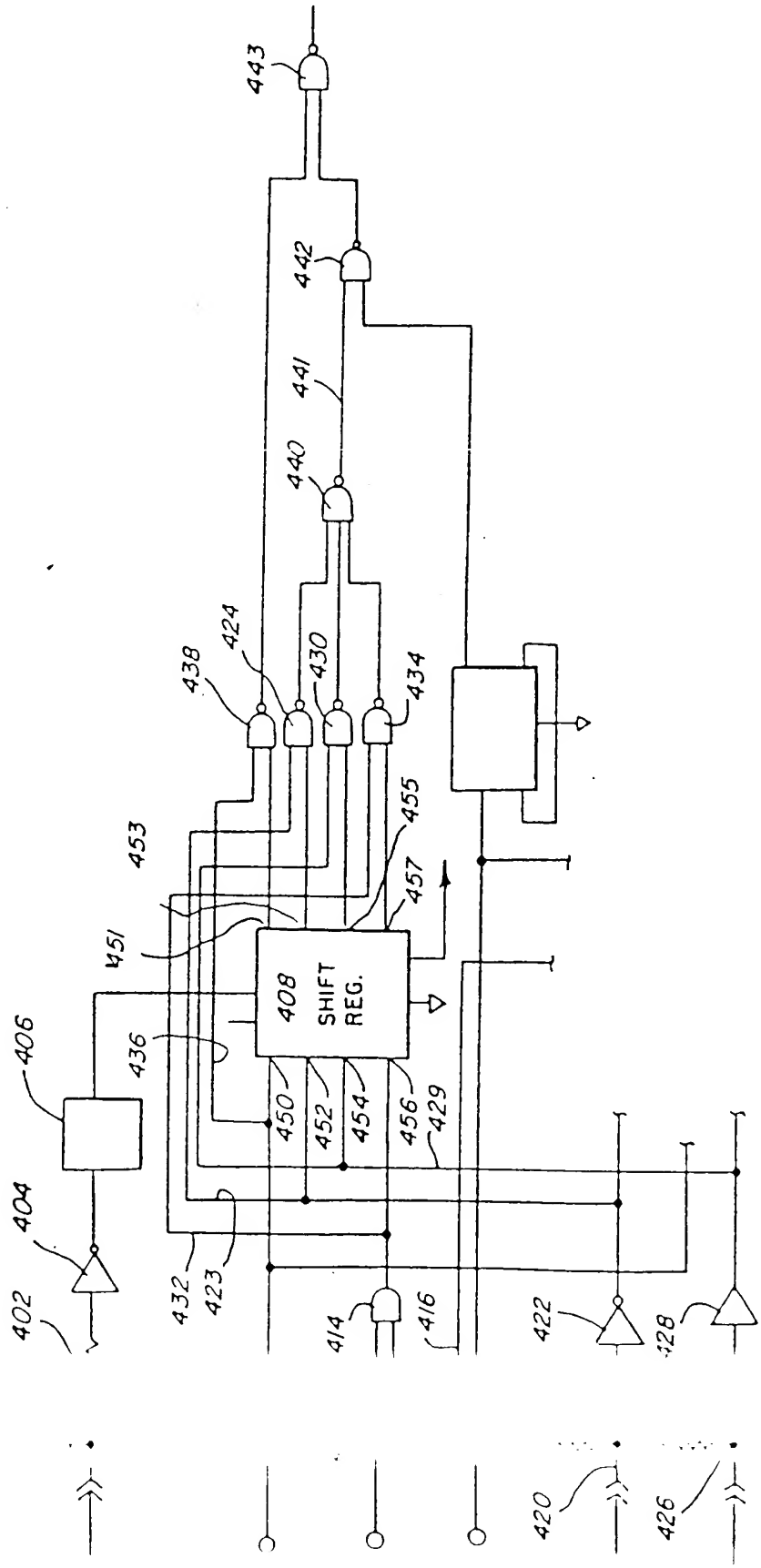


FIG. 13



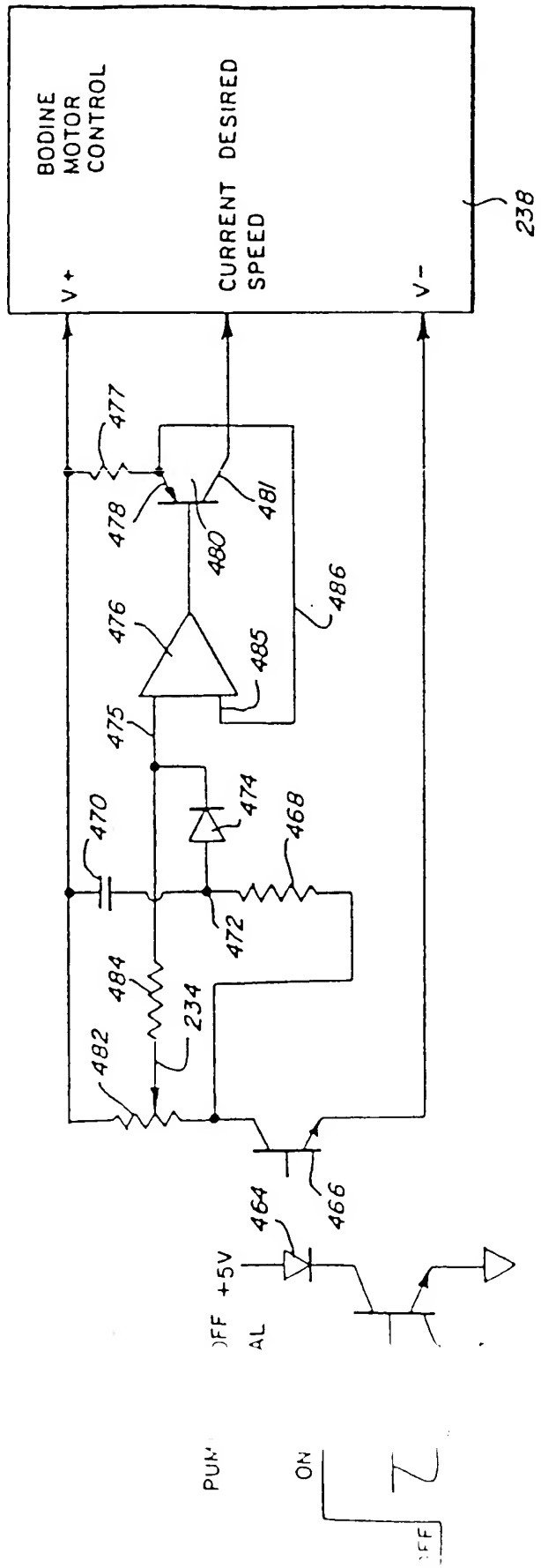
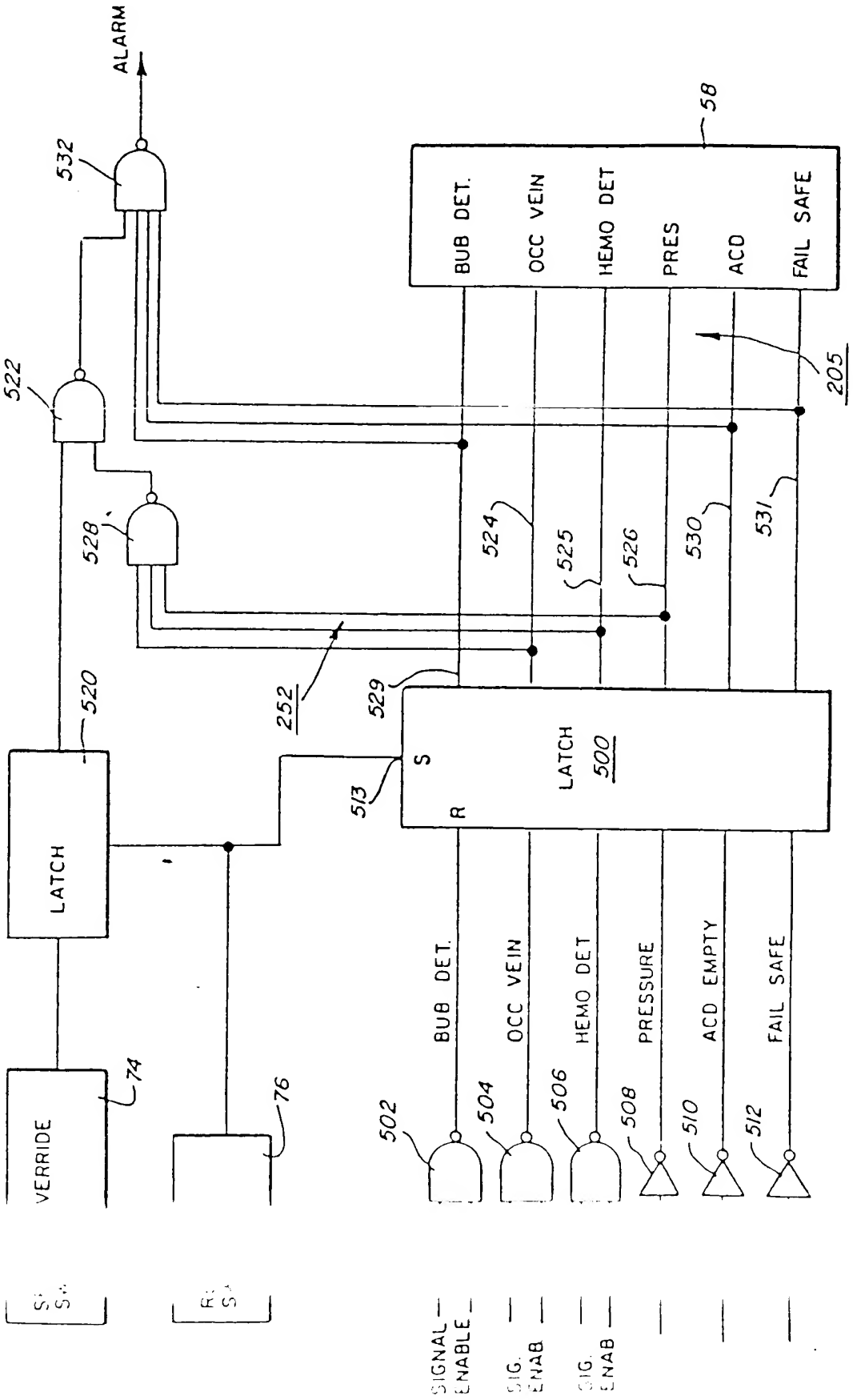


FIG. 14

FIG. 15



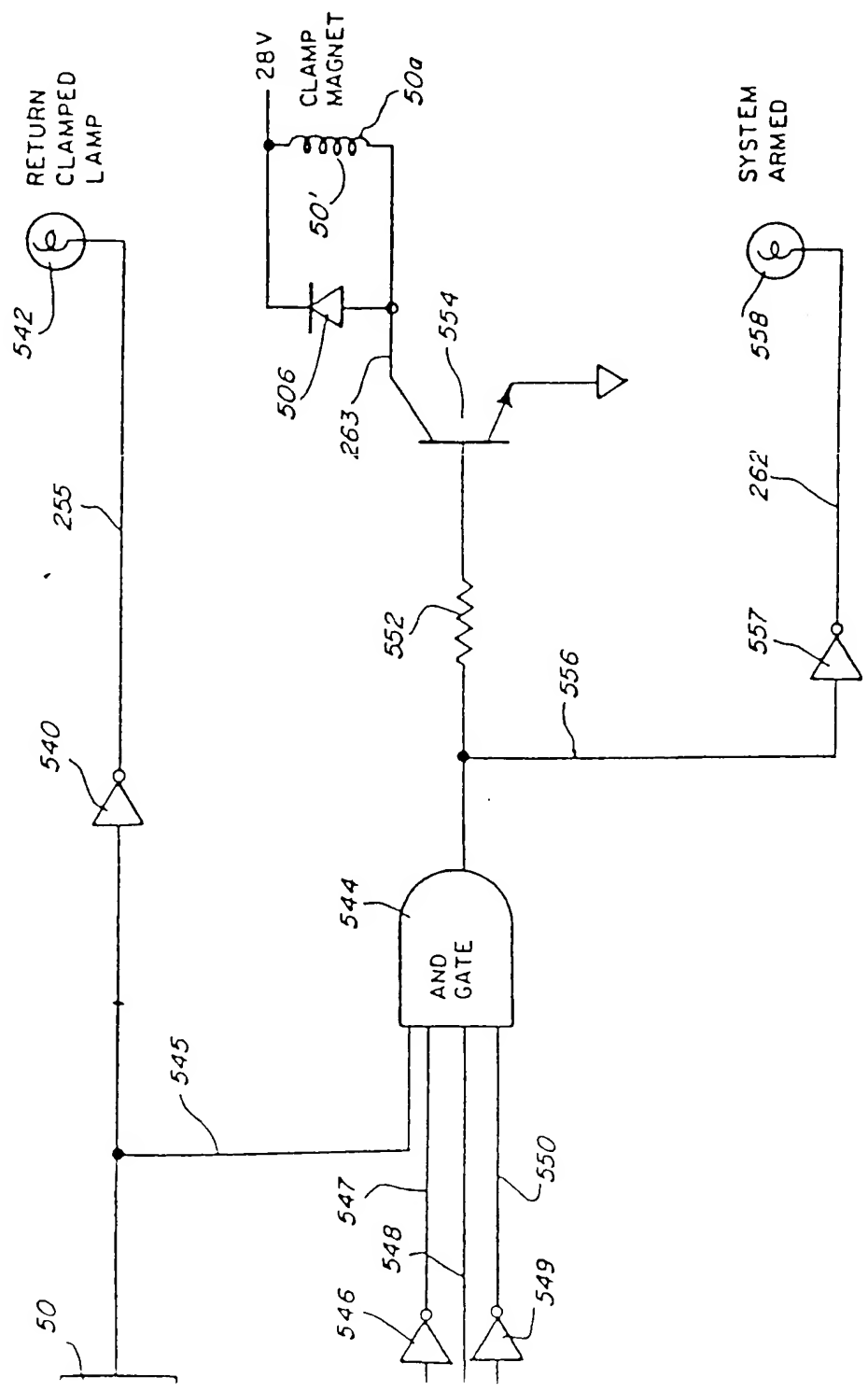


FIG. 16

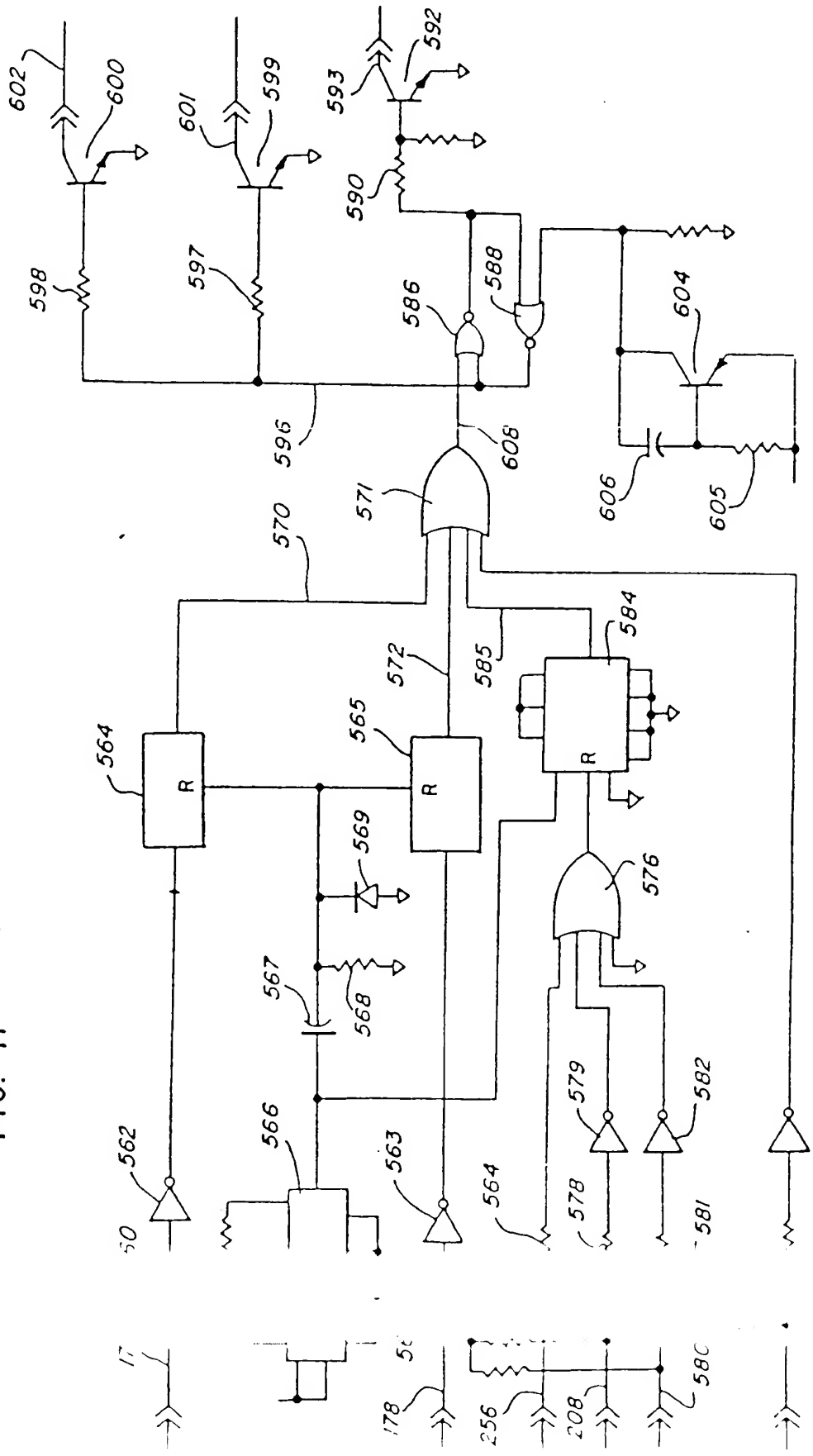
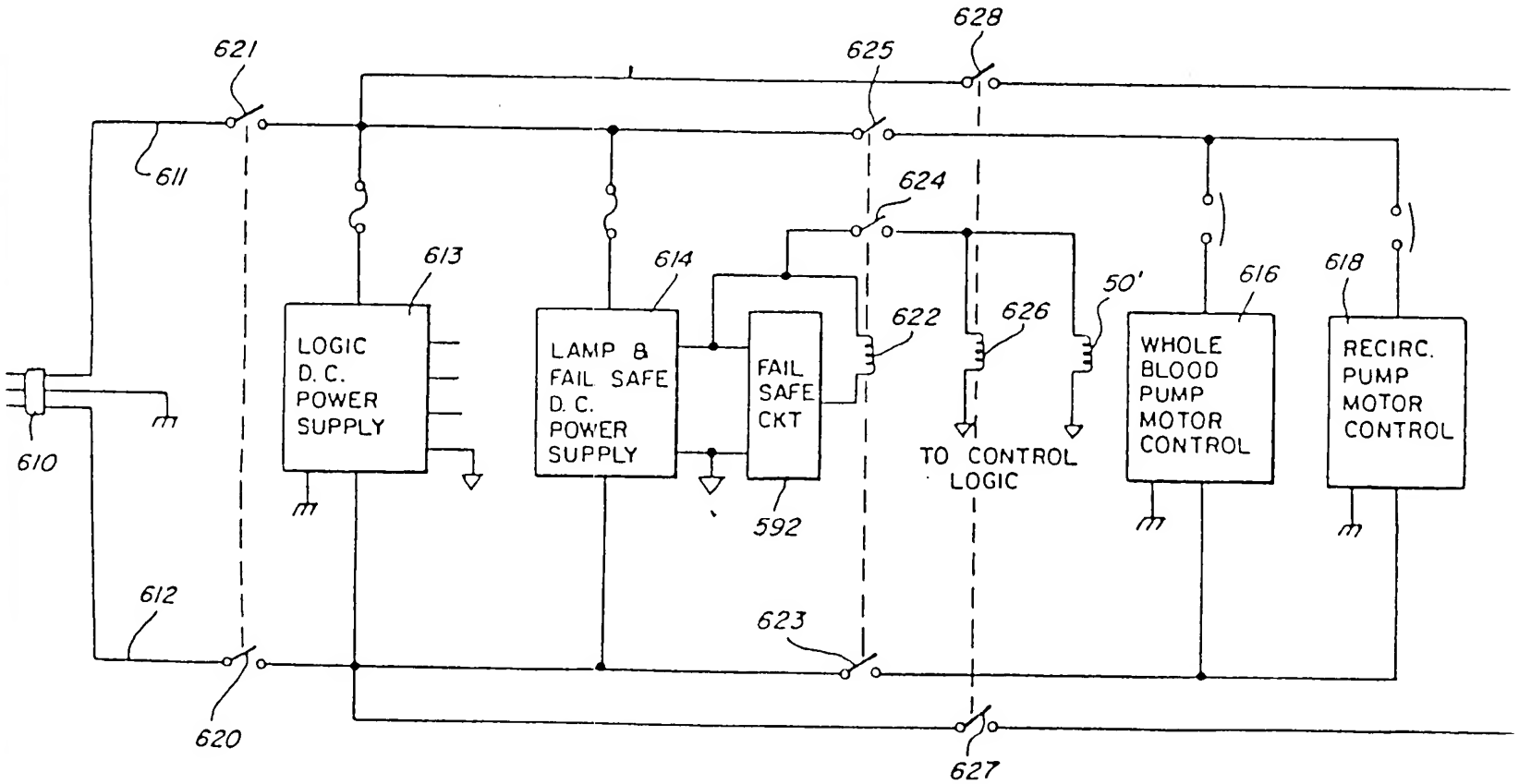


FIG. 17

FIG. 18



INTERNATIONAL SEARCH REPORT

International Application No PCT/US81/00334

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) *

According to International Patent Classification (IPC) or to both National Classification and IPC

Int. Cl.[3] A61M 1/03, 5/00

US Cl. 128/214R,214B,214E,214F

II. FIELDS SEARCHED

Minimum Documentation Searched *

Classification System	Classification Symbols
US	128/214R,214B,214E,214F

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched *

III. DOCUMENTS CONSIDERED TO BE RELEVANT **

Category *	Citation of Document, ** with indication, where appropriate, of the relevant passages **	Relevant to Claim No. **
	WO,A, 79/01121, Published 27 December 1979	1-65
	DE,A, 2725608, Published 05 January 1978	1-65
	US,A, 4,185,629, Published 29 January 1980 CULLIS, et al	1-65
	US,A, 4,086,924, Published 02 May 1978 LATHAM, JR	1-65
P	US,A, 4,227,526, Published 14 October 1980 GOSS	1-65
	US,A, 3,946,731, Published 30 March 1976 LICHTENSTEIN	1-65
	US,A, 3,648,694, Published 14 March 1972 MOGOS, et al	1-65
	US,A, 4,111,198, Published 05 September 1978 MARX, et al	1-65
AP	US,A, 4,210,138, Published 01 July 1980 JESS, et al	4,17-19
A	SU,A, 599310 Published 07 April 1978	1-65
A	DE,A, 1566562, Published 15 January 1970	1-65

* Special categories of cited documents: **

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"E" earlier document but published on or after the international filing date

"L" document cited for special reason other than those referred to in the other categories

"P" document published prior to the International filing date but on or after the priority date claimed

"T" later document published on or after the international filing date or priority date and not in conflict with the application, but cited to understand the principle or theory underlying

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
16 July 1981	29 JUL 1981

International Searching Authority *	Signature of Authorized Officer **
ISA/US	S. Brattli

Form PCT/ISA/210 (second sheet) (October 1977)

4501719

International Application No PCT/US 82/00106

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [8]

According to International Patent Classification (IPC) or to both National Classification and IPC

INT. CL.[3] B01D 13/02
US. 204/180P

II. FIELDS SEARCHED

Minimum Documentation Searched [4]

Classification System	Classification Symbols
US	204/180R, 180P, 301

Documentation Searched other than Minimum Documentation to the Extent that such Documents are included in the Fields Searched [6]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]	Relevant to Claim No. [18]
X	US, A, 1,472,316, Published, 30 October 1923, Zeissler	1-13, 22-24
X	US, A, 4,216,205, Published, 05 August 1980, Radowitz	20,28
P,X	US, A, 4,276,140, Published, 30 June 1981, Jain	1-28

* Special categories of cited documents: [15]

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"X" document of particular relevance

Date of the Actual Completion of the International Search [2]	Date of Mailing of this International Search Report [2]
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